APPENDIX A

175 Fed. Appx. 329, 2006 WL 678921 (C.A.Fed.)

This case was not selected for publication in the Federal Reporter. NOTE: Pursuant to Fed.Cir.R. 47.6, this order is not citable as precedent. It is public record.

United States Court of Appeals, Federal Circuit.

ARLAINE & GINA ROCKEY, INC., Plaintiff-Appellant,

v.

CORDIS CORPORATION, Defendant-Appellee.

No. 05-1236.

March 16, 2006.

Rehearing Denied April 11, 2006.

Before MICHEL, Chief Judge, SCHALL, and GAJARSA, Circuit Judges.

GAJARSA, Circuit Judge.

Arlaine & Gina Rockey, Inc. ("AGR") appeals from the district court's grant of summary judgment in favor of Cordis Corp. ("Cordis"). The district court found that AGR is not entitled to royalties under ***330** its licensing agreement with Cordis because the use of Cordis' accused device (the "Palmaz-Schatz" stent) is not covered by claim 2 of AGR's stent patent, U.S. Patent No. 4,641,653. On July 1, 2002, AGR filed this action in the Circuit Court for Miami-Dade County, Florida, alleging breach of the licensing agreement, breach of an implied duty to commercialize, and breach of the duty of good faith and fair dealing. The case was removed to federal

court pursuant to 28 U.S.C. § 1441. The district court denied AGR's remand request but did certify the question for interlocutory review. This court denied AGR's petition for interlocutory review of the district court's refusal to remand to the state court. *See Arlaine & Gina Rockey, Inc. v. Cordis Corp.*, 68 Fed. Appx. 185 (Fed.Cir.2003). Subsequently, the trial court conducted a *Markman* hearing and issued a claim construction order. AGR then filed a motion for reconsideration of the claim construction while Cordis submitted a motion for summary judgment. The district court denied AGR's motion for reconsideration of the claim construction and granted summary judgment in favor of Cordis. AGR filed a timely appeal. For the reasons stated below, we *affirm*.

BACKGROUND

During the late 1970's, Dr. Arthur G. Rockey experimented with methods of treating problems with blood vessels and the gastrointestinal tract using medical devices called stents. From this research, he applied for and received United States Patent Nos. 4,501,264, 4,641,653, and 4,763,653 (collectively, "the Rockey Patents"), all of which he later assigned to AGR. The Rockey Patents cover various medical devices and procedures involving stents. This appeal concerns only Patent No. 4,641,653 (" '653 patent").

In 1995, AGR granted Cordis an exclusive world-wide license to the Rockey Patents, which included *inter alia* the right to sell devices, the use of which is protected by AGR's method claims. As compensation, Cordis agreed to pay AGR an advance or pre-paid royalty of two-million dollars and a 10% royalty on all related products sold exceeding twenty-million dollars. AGR claims that Cordis breached the license agreement by selling the accused device, the Palmaz-Schatz stent, without paying royalties thereon.

Claim 2 of the '653 patent is directed to a method for inserting a stent into a blood vessel, manipulating the stent into position, and expanding it to the full diameter of the vessel.

The stent remains in place due to the frictional forces created by the expanded device against the blood vessel wall, and helps to maintain an open passageway in a diseased vessel.

Likewise, the Palmaz-Schatz stent is used in a similar manner. There are, however, important differences. The Palmaz-Schatz stent is a lattice-like cylinder that is delivered to a desired location within the blood vessel and then radially expanded by an internal balloon. The expanding balloon causes permanent deformation of the latticed-steel cylinder. The metal of the stent retains its new shape, just as a paper clip maintains its new shape after bending. The cylinder is, of course, an integral part of the stent.

In contrast, the '653 patent illustrates the use of a stent that has a different means of maintaining itself in a permanently expanded configuration. Rather than relying on mechanical deformation of a steel-lattice, the Rockey patent relies on the introduction of a slowly-hardening substance. In a typical embodiment this is a gel that cross-polymerizes and slowly increases in rigidity, until it sets in a permanently rigid conformation. These stents ***331** are typically referred to as "Gastra" stents.

Based on the claim construction, the district court found that the use of the Palmaz-Schatz stent does not infringe the '653 patent and that therefore no additional royalties were due to AGR pursuant to the license. Thus, the district court granted summary judgment in favor of Cordis. AGR appeals this decision.

JURISDICTION

The Federal Circuit has exclusive jurisdiction over appeals from a district court's final decision when the "jurisdiction of that court was based, in whole or in part, on section 1338." 28 U.S.C. § 1295(a). Section 1338 provides that the "district courts shall have original jurisdiction of any civil ac-

tion arising under any Act of Congress relating to patents." 28 U.S.C. § 1338(a).

AGR premised its cause of action against Cordis on a licensing agreement, which is a matter of state contract law.[1] The court must determine whether or not jurisdiction is appropriate. *See In re Compagnie Generale Maritime,* 993 F.2d 841, 848 (Fed.Cir.1993) (stating that courts can raise issues of subject matter jurisdiction *sua sponte* at any time). In order to prevail on its claim for royalties, AGR must establish entitlement under the contract. This court has jurisdiction under section 1295 when "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." *U.S. Valves, Inc. v. Dray,* 212 F.3d 1368, 1372 (Fed.Cir.2000) (*quoting Christianson v. Colt Indus. Operating Corp.,* 486 U.S. 800, 809, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988)). To prevail in its contract action for royalties, AGR must show that the use of Cordis' products was infringing the patent. *Id.* As a result, AGR's right to relief depends on the resolution of a substantial question arising under the patent law. *Id.* Therefore, this court has jurisdiction because the underlying cause of action arises under patent law. 28 U.S.C. § 1338(a).

DISCUSSION

At issue in this appeal is whether the use of the Palmaz-Schatz stent infringes the '653 patent. AGR argues that the district court erred by improperly importing limitations of the preferred embodiment into the claims in its claim construction and that under a proper construction, there exist genuine issues of material fact regarding infringement.

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[1] AGR alleges other counts as well, but these also involve issues of state law, and none would be sufficient to provide a basis for § 1338 jurisdiction. Thus, this case does not involve issues of supplemental jurisdiction under § 1367(a).

We review a grant of summary judgments *de novo*. *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed.Cir.1998). Summary judgment is applied when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. Pro. 56(c); *Ethicon*, 149 F.3d at 1315. Summary judgment may be granted when no "reasonable jury could return a verdict for the nonmoving party." *Ethicon*, 149 F.3d at 1315 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). In order to determine whether summary judgment was appropriately granted, we view the evidence in the light most favorable to the nonmoving party. *Id.*

Determining patent infringement is a two-step process consisting of the court construing the claims and then comparing the allegedly infringing device to the property construed claims. *See* ***332** *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1295 (Fed.Cir.2005). The first step, claim construction, is a matter of law, which we review *de novo*. *Id.* The second step is typically a factual question, which we review for clear error; "however, where the factual inferences are material to the grant of summary judgment, we review them to ascertain whether there is a genuine issue of material fact." *Id.*

A. Claim Construction

To construe claims, we first consider the ordinary and customary meaning of the claim language. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (*en banc*). The claim's "ordinary and customary meaning" is the reading a person of ordinary skill in the art would give the claim at the time of the invention. *Id.* at 1313. The person of ordinary skill in the art should read the claim term "not only in the context of the particular claim in which the disputed terms appears, but in the context of the entire patent, including the

specification." *Id.* Claim 2 of the '653 patent reads as follows:

> A method of treating an area of a body vessel, comprising the steps of:
>
> [1] introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated;
>
> [2] manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated;
>
> [3] inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel;
>
> [4] *providing in* the sleeve *a material* which increases in rigidity after expansion of said balloon;
>
> [5] maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity; and
>
> [6] thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in the area to be treated

(emphases added, bracketed numbers added)

AGR argues that the district court's claim construction was not justified and urges us to adopt a different claim construction. The district court defined "providing in the sleeve a material which increases in rigidity after expansion of said balloon" to mean "supply[ing] in the sleeve a material that is separate and distinct from the sleeve itself." It rejected AGR's argued-for construction that this limitation somehow means that the sleeve has been *pre-formed* with a material that increases in rigidity after the balloon expansion. Rather,

the district court held that the limitation requires the addition of a material to the stent at some point in the process.

When interpreting the claims, we must read them " 'in view of the specification, of which they are a part.' " *Phillips,* 415 F.3d at 1315 (quoting *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 978 (Fed.Cir.1995) (*en banc*)). In interpreting the '653 claim, the district court considered the intrinsic evidence contained in the patent specification to determine the meaning of the term "provided in." AGR's argument that the sleeve has been pre-formed with the material that increases in rigidity is without merit. The written description establishes that if the inventor intended to claim that the material was part of the invention, he would not have used the term "providing." In a description of one of the ***333** preferred embodiments, the specification speaks of the "sleeve unit ... *including* the ring balloons," which are intended to be filled with fluid, being *"provided* with sufficient radiopaque material...." '653, col. 4, ll. 43-45 (emphasis added). Moreover, in another preferred embodiment, the specification speaks of the "sleeve space ... *contain[ing]* a fluid plastic material ... which is caused to become solidified ...," and *"introduc[tion]* into the sleeve space" of such material. *Id.* col. 6, ll. 22-26 (emphasis added). In short, the specification makes clear that in drafting his claims, when the patentee used the word "providing"-a word that like "introduc[ing]" or "supplying" denotes the addition of a separate substance into the stent-he did so deliberately, and not through an accident of quirky or idiomatic usage. This conclusion can be drawn from the fact that when he meant to convey the preexistence of a material in the sleeve he used an appropriate verb, such as "contain[ing]." *Id.*

Similarly, when Dr. Rockey wanted to convey the idea "formed of a material" he so stated specifically. In a description of one of the embodiments, the patent states that the "balloon ... is *formed* of any suitable plastic or rubber material." *Id.,* col. 6, ll. 7-9 (emphasis added). In another example, the

specification teaches that an "outer sleeve wall ... may be *formed* of Dacron" and an "inner wall ... may be *formed* of Teflon." *Id.*, col. 6, ll. 16-17 (emphasis added). Finally, the patent teaches that "the sleeve ... is preferably *formed* of relatively inelastic material." *Id.*, col. 5, ll. 52-53 (emphasis added). Thus, Rockey used the term "formed of" throughout the patent, yet specifically claimed the method of "providing in" for the claim involving the material. Considering this intrinsic evidence, we agree with the district court's construction of the fourth claim limitation.

B. Applying the Claim Construction to the Accused Device

In light of this claim construction, we hold that the district court did not err in finding that there is no genuine issue of material fact whether the use of the Palmaz-Schatz stent is covered by the '653 patent. The district court construed the method of "providing in ... a material" to mean "supplying in ... a material." The use of the Palmaz-Schatz stent does not satisfy this limitation. Unlike the material added in the method described in the '653 patent, the Palmaz-Schatz stent steel-cylinder lattice is *part of* the stent and is not "introduced" or "supplied." No reasonable jury could conclude otherwise. Therefore, use of the Palmaz-Schatz stent does not infringe the '653 patent. Thus, Cordis is not subject to royalty payments pursuant to the terms of the license agreement for the Palmaz-Schatz stent.

C. Doctrine of Equivalents

Finally, we address AGR's doctrine of equivalents argument. AGR asks this court to accept the proposition that the limitation of "providing ... a material" is equivalent to a method in which no material has been provided in accordance with the required step. This argument is without merit because the application of the doctrine of equivalents in this situation would vitiate the "providing in" limitation. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379

(Fed.Cir.2005). AGR argues that the "provided in" limitation is extraneous, meaning that it has little significance to the patent. Under the all-elements rule, however, there are no extraneous limitations. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) ("Each element contained in a patent claim is deemed material to defining ***334** the scope of the patented invention...."). Thus, the district court did not commit error.

Because the district court did not err in its claim construction and correctly compared the asserted claim with the accused device, we affirm.

APPENDIX B

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION
Case No: 02-22555-CIV-ALTONAGA/Bandstra

ARLAINE & GINA ROCKEY, INC.,

Plaintiff,

vs.

CORDIS CORPORATION,

Defendant.

_____/

ORDER ON PENDING MOTIONS, AND SETTING STATUS CONFERENCE

THIS CAUSE came before the Court upon the following pending motions: (1) Plaintiff, Arlaine & Gina Rockey, Inc.'s ("AGR") Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents **(D.E. 102)**; (2) AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony **(D.E. 103)**; (3) AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph Puma **(D.E. 104)**; (4) AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony **(D.E. 105)**; (5) AGR's Motion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection **(D.E. 106)**; (6) Defendant, Cordis Corporation's ("Cordis") Motions *in Limine* to Exclude Parol Evidence, to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on Products that Practice the Rockey Patents "In Whole Or In Part," to Exclude or Limit the Testimony of

AGR's Patent Law Experts, to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents, and to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert* **(D.E. 108)**; (7) Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985 for Claim 2 of the '1,653 Patent **(D.E. 121)**; (8) Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard **(D.E. 150)**; (9) Cordis' Motion for Summary Judgment **(D.E 45)**; and (10) Cordis' Motion for Construction of Terms in the Claims of the Rockey '1,653 Patent **(D.E. 107)**. The Court has reviewed the Motions, the response and reply memoranda, and the pertinent portions of the record. The Court also heard oral argument on the Motions on August 28, 2003 and October 31, 2003.

I. FACTUAL BACKGROUND[1]

A. THE PARTIES

During the late 1970's, Dr. Arthur G. Rockey ("Dr. Rockey"), a podiatrist, began experimenting with methods of treating various problems with body cavities, namely blood vessels and the gastrointestinal tract. He developed a number of medical inventions, and the U.S. Patent and Trademark Office ("PTO") issued Dr. Rockey three patents, including United States Patent No. 4,501,264, issued on February 26, 1985 (the "'1,264 Patent"); United States Patent No. 4,641,653, issued on February 10, 1987 (the "'**1,653 Patent**"); and United States Patent No. 4,763,653, issued on August 16, 1988 (the "'3,653 Patent") (collectively the "Rockey Patents"). All three patents concern methods of using a medical sleeve. Dr. Rockey passed away in 1987, one year before his third patent was issued.

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[1] The facts are taken from the Statements of Facts submitted by the parties and from the documentary and testimonial evidence before the Court, and are undisputed unless otherwise noted.

AGR is a Wyoming corporation formed in 1992 to market and commercially exploit Dr. Rockey's inventions. The shareholders of AGR are Dr. Rockey's two daughters, attorneys Arlaine Rockey and Gina Rockey Collias, and his widow. AGR owns the three U.S. patents issued to Dr. Rockey.

Cordis is a Florida corporation with its headquarters in Miami Lakes, Florida. It was founded in 1959, and Johnson & Johnson ("J & J") acquired Cordis in February 1996. Cordis is a leader in marketing stents for use in coronary arteries and other body passageways. As a result of the acquisition, a J & J subsidiary that had been selling metal stents became a Cordis affiliate. That subsidiary was merged into Cordis, and thus Cordis has been selling balloon-expandable metal stents based on inventions by Dr. Julio Palmaz ("Dr. Palmaz") and Dr. Richard Schatz ("Dr. Schatz") since 1996.

B. THE ROCKEY '1,653 PATENT AND ITS PROSECUTION HISTORY

Dr. Rockey filed his first application for a "Medical Sleeve" on June 2, 1978, and it was assigned U.S. Patent Application No. 912,010 (the "'010 Application"). The '010 Application disclosed two embodiments of an invention for a medical sleeve, one for a stomach sleeve and the other for a graft in the aorta or common iliac arteries. The '010 Application did not mature into an issued patent and was later abandoned. However, Application Serial No. 216,989 (the "'989 Application") was filed on December 16, 1980 as a continuation-in-part of the '010 Application and became the '1,264 Patent in 1985.

Subsequently, Application Serial No. 702,828, which was filed on February 19, 1985, became the '1,653 Patent on February 10, 1987. The '1,653 Patent application added a new figure (Figure 9) and also added new text that describes the embodiment that is depicted in Figure 9. Figure 9 shows a balloon catheter used to deliver a sleeve to a treatment site.

Pressurized fluid travels through the catheter to the balloon and is used to inflate the balloon. The balloon and catheter are then removed from the body, leaving the sleeve in place in the area to be treated.

In this lawsuit, AGR contends that the Palmaz stent, the Palmaz-Schatz stent and more recent stents sold by Cordis are all covered by **one** claim of **one** licensed Rockey Patent - claim 2 of the '1,653 Patent. Claim 2 of the Patent is a method claim that describes a method of using a sleeve with specified characteristics to treat an area of a body vessel. The claimed method includes six action steps. Claim 2 reads in its entirety as follows:

> 2. A method of treating an area of a body vessel, comprising the steps of:
>
> [a] introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated;
>
> [b] manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated;
>
> [c] inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel;
>
> [d] providing in the sleeve a material which increases in rigidity after expansion of said balloon;
>
> [e] maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity; and
>
> [f] thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated.

Dr. Rockey's final application, Application Serial No. 11,335, was filed on February 5, 1987 and issued on August 16, 1988 as the '3,653 Patent. All three patents describe a method and article for medical diagnosis and/or treatment of body disorders, comprising a sleeve unit that may be inserted into a natural body vessel to isolate material flowing into the vessel from direct contact with the interior surface of the vessel. The first two patents, the '1,264 Patent and the '1,653 Patent, specifically address the treatment of obesity.

Cordis' position is that Dr. Rockey's earliest possible "priority date" for the invention disclosed in the '1,653 Patent is the date when the application for the '1,653 Patent was filed-February 19, 1985. AGR argues that the June 2, 1978 filing date of the '010 Application is the "priority date" that should be applied to the claims of the '1,653 Patent. There is also conflicting evidence regarding whether each of the limitations of claim 2 of the '1,653 Patent was disclosed in the previous '010 Application, as required for the earlier filing date to apply. The experts differ as to whether the '010 Application and the '989 Application disclose the steps described in claim 2 of the '1,653 Patent of **removing** the catheter and balloon from the vessel at the end of the procedure, and providing in the sleeve a material that increases in rigidity after expansion of the balloon.

C. THE PALMAZ, PALMAZ-SCHATZ AND OTHER STENTS SOLD BY CORDIS

Until 1994, the main treatment for opening up blocked arteries was balloon angioplasty. Angioplasty had serious drawbacks, and researchers were looking for a better treatment. Those researchers included Dr. Palmaz and his colleague, Dr. Schatz.

At the heart of this case is the issue of who is the true and first inventor of the balloon-expandable stent. Sometime in the late 1970's or early to mid 1980's, Dr. Palmaz began work on what was to become known as the Palmaz or the

Palmaz-Schatz balloon-expandable stent. Dr. Palmaz allegedly conceived of his invention sometime between 1978 and 1984. He has testified that, working in his garage in the late 1970's, he invented the balloon-expandable stent. Back in 1980, Dr. Palmaz had described his invention in detail in a written "monograph." And, in the early 1980's, Dr. Palmaz made prototype stents and successfully implanted them in dogs.

Dr. Palmaz has testified that he conceived of his invention after attending a lecture by Dr. Andreas Gruntzig, who is known as the father of balloon angioplasty. Dr. Gruntzig explained his idea of balloon angioplasty as a method of treating vascular disease. Dr. Gruntzig also described some of the complications associated with using angioplasty as a treatment. At his lecture, Dr. Gruntzig performed one of the first live demonstrations of angioplasty in the United States, and many of the complications that Dr. Gruntzig described occurred. Upon hearing about and seeing these complications, Dr. Palmaz claims that he conceived the idea of using a scaffolding that would be delivered on and expanded by an angioplasty balloon, and would be left behind to support the vessel wall, ameliorating the dire complications of angioplasty. Dr. Palmaz then worked diligently on his invention for the next several years, leading to a successful implantation in an animal in 1984.

The facts provided by Dr. Palmaz relating to his conception date are all disputed by AGR. There is some evidence, however, that corroborates Dr. Palmaz's version of events, including Dr. Palmaz's copy of the program from Dr. Gruntzig's lecture with Dr. Palmaz's handwritten notations, hotel and airline receipts for Dr. Palmaz's trip to attend the lecture, receipts for materials that Dr. Palmaz ordered for the purpose of making prototypes of his invention, written monographs in which Dr. Palmaz explains his research, correspondence showing Dr. Palmaz's attempts to interest companies in

his inventions, and x-rays of successful implants of Dr. Palmaz's stent in dogs.

Dr. Palmaz filed his first patent application, Application Serial No. 796,009 (the "796,009 Application"), for his balloon-expandable metal stent on November 7, 1985, which issued as U.S. Patent No. 4,733,665 (the "Palmaz '3,665 Patent"). The Palmaz '3,665 Patent describes an "expandable intraluminal vascular graft [that] is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel." Dr. Palmaz was issued a second patent for a related invention on April 26, 1988, which was assigned U.S. Patent No. 4,739,762 (the "Palmaz '9,762 Patent"). Dr. Palmaz filed the application for the '9,762 Patent, which was a continuation-in-part application of the earlier 796,009 Application, on November 3, 1986, and it was assigned Application Serial No. 923,798. On March 29, 1988, the PTO extended the patent term of the Palmaz '3,665 Patent for 182 days pursuant to an application made by the Patent owner under 35 U.S.C. § 156. Palmaz achieved his first approval from the Food and Drug Administration ("FDA") for a balloon-expandable stent on September 27, 1991.

On February 19, 1991, Dr. Schatz filed his first patent application for an "expandable intraluminal graft," Application No. 657,296. It was issued on March 23, 1993 as U.S. Patent No. 5,195,984. Dr. Schatz's second patent, U.S. Patent No. 5,800,516, for a "deployable and retrievable shape memory stent/tube and method," issued on September 1, 1998, and derived from Application No. 693,708 filed on August 8, 1996.

Other patents for stents sold by Cordis include: (1) the "deployable and retrievable shape memory stent/tube and method," U.S. Patent No. 5,800,516, issued on September 1, 1998, based on Application No. 693,708 filed on August 8, 1996 by inventor, Michael J. Fine; (2) the "method for mak-

ing a multi-laminate stent having super elastic articulated sections," U.S. Patent No. 6,425,855 B2, issued on July 30, 2002, based on Application No. 09/852,094 filed on May 9, 2001 by inventor, Charles V. Tomonto; and (3) the "covered expanding mesh stent," U.S. Patent No. 5,968,070, issued on October 19, 1999, based on Application No. 08/909,520 filed on August 11, 1997 by inventor, Robert S. Bley.[2] The products patented by the Palmaz and Schatz Patents and the Rockey '1,653 Patent are the inventions at issue in this litigation, although the other patents and inventions are also considered.

The Palmaz and Schatz stents, and a more recent BX Velocity stent sold by Cordis, are small lattice-like structures that are made of a single material, medical grade stainless steel, *i.e.* 316L stainless steel. (Declaration of David C. Majercak ("Majercak Decl."), ¶ 3). Cordis does not provide a separate material in the stent that is separate and distinct from the stent itself, and physicians also do not provide in Cordis' balloon-expandable stents a material that is separate and distinct from the stents themselves. (Majercak Decl., ¶ 11; Declaration of Joseph A. Puma ("Puma Decl."), ¶ 33). The metal stents are implanted in patients' arteries and serve as scaffolding to maintain open passageways in arteries that have been narrowed by disease.

Cordis has proferred some evidence indicating that the Cordis stents are not folded upon themselves, (Majercak Decl., ¶¶ 4-5), and that in using a Cordis balloon-expandable stent, physicians do not fold the stent upon itself. (Puma Decl., ¶ 22). AGR admits that physicians do not fold the Cordis stents upon themselves during their use of the stents. However, the experts disagree as to whether Cordis' stents are "folded together compactly" so that one part is laid over another part. (*See, e.g.*, Deposition of Edward F. Leonard

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[2] All of these stents, sold By Cordis since May 15, 1995, are referred to in this Order as "Cordis' stents" or "the Cordis stents."

("Leonard Depo."), 94:3-10; 95:12-15; 96:1-4; 103:725; 104; 105; 108:24-25; 109:1-10) (the Cordis stent is "folded compactly" and doubled over with one part lying over another part); Puma Decl. ¶¶ 20-22 ("[I]ts [Cordis'] stents are not 'folded,' that is, no part of the stent is laid over another part. The stent is never doubled upon itself"); Deposition of George P. Widas ("Widas Depo."), 92:21-24; 93:1-4 (the Cordis stent is not "bent upon itself")).

When Cordis' balloon-expandable stents are mounted on a balloon catheter, there is a portion of the **balloon** that extends beyond the stent, (Majercak Decl., ¶ 6; Puma Decl., ¶ 26), and when Cordis' balloon-expandable stents are mounted on a balloon catheter, there is a portion of the **catheter** that extends beyond the stent. (Majercak Decl., ¶ 7; Puma Decl., ¶¶ 28-29). Cordis' balloon-expandable stents are not positioned on the extreme or last portion lengthwise of the balloon, or on the extreme or last portion lengthwise of the catheter (Majercak Decl., ¶¶ 6-9), and physicians do not place Cordis' balloon-expandable stents on the extreme or last portion lengthwise of the balloon or of the catheter. (Puma Decl., ¶¶ 28-29). The experts disagree as to whether the Cordis stents are placed at or near an extremity of the catheter. (*See, e.g.*, Leonard Depo., 111:11-25; 224:10-20) (Cordis' stent is located near the end of the catheter); Puma Decl., ¶¶ 23-29) (Cordis' stent is not located at or near the end of the catheter; rather, it is located "at a distance"); *and see* Majercak Decl., ¶¶ 6-8 ("Cordis' stents and the balloon on which they are mounted are positioned so that the end of the catheter extends a distance beyond the stent and balloon.").

In the early 1990's, Dr. Palmaz's and Dr. Schatz's concept of a balloon-expandable stent was the subject of two large-scale clinical trials commissioned by J & J, which had taken a license in the Palmaz and Schatz Patents in 1986. Results from those clinical trials were published in the New England Journal of Medicine in August 1994. They showed that the Palmaz-Schatz stent was safe, effective and superior

to angioplasty. Within weeks, the FDA approved the Palmaz-Schatz balloon-expandable stent for sale in the United States, and stenting quickly replaced angioplasty as the standard of care. Stents embodying the Palmaz and Schatz inventions have been used to treat millions of patients.

D. THE LICENSE AGREEMENT

In 1994, AGR began to negotiate with Cordis regarding granting Cordis world-wide exclusive rights to the inventions disclosed and claimed in the Rockey Patents. On January 24, 1995, Cordis and AGR entered into a Confidential Disclosure Agreement. On March 2, 1995, pursuant to the terms of the Confidential Disclosure Agreement, Cordis disclosed to AGR information regarding Cordis' projections of the commercial market for balloon-expandable stent products covered by the claims of the Rockey Patents. That information included Cordis' substantial sales and royalty forecasts based upon Cordis' expected commercialization of the technology disclosed and claimed in the Rockey Patents.

The License Agreement between Cordis and AGR was executed on May 15, 1995. The License Agreement granted Cordis an "exclusive world-wide license to manufacture, have manufactured, use and sell devices or products incorporating, in whole or in part any and all of the inventions and improvements disclosed or claimed in the [Rockey] Patents." (License Agreement, § 2.1). Cordis would also "have the right to sublicense any Affiliate, or any third party who is not an Affiliate under the Patents to manufacture, use and sell devices or products incorporating in whole or in part any and all of the inventions and improvements disclosed or claimed in the Patents." (License Agreement, § 2.2). The "Patents" covered by the License Agreement are the three Rockey Patents and any and all continuations, continuations-in-part, divisions, reissues and foreign patent applications, and patents based on such Patents. (License Agreement, § 1.1.2). "Licensed Products" are defined as products which are "(i) sold,

or (ii) used in a medical procedure, in a country where it is covered by any claim of the Patents." (License Agreement, § 1.1.2). "'Affiliate' means any entity which, directly or indirectly, controls or is controlled by, or is under common control with, Cordis." (License Agreement, § 1.1.5). J & J, the company that subsequently acquired Cordis, owns various organizations throughout the world, some of which are involved in the manufacture, use and sale of balloon-expandable stents. As defined by the License Agreement, J & J's Interventional Systems Company division constitutes an affiliate company of Cordis.

With regard to compensation, the License Agreement provided that Cordis would pay AGR advance or pre-paid royalties (the "Advance") of $2,000,000, comprising the following payments: (i) $500,000 upon execution of this agreement; (ii) $500,000 on July 1, 1995; and (iii) eight equal installments of $135,000 each, commencing on July 1, 1996, and every three months thereafter, up to the amount of $1,000,000. (License Agreement, § 3.1). The Agreement further provides that:

> [c]ommencing on the date ("Royalty Date") that Cordis, its Affiliates, and Sublicensees have cumulatively (i) sold, or (ii) used in a medical procedure, Licensed Products (not including any Licensed Products (i) sold, or (ii) used in a medical procedure, before the Commercialization Date) having an aggregate Net Selling Price equal to $20,000,000 (such amount, the "Advance Sales"), Cordis shall pay to Licensor [AGR] a running royalty (the "Running Royalty") equal to 10% (the "Royalty Rate") of the Net Selling price of all Licensed Products (i) sold, or (ii) used in a medical procedure .... [N]o Running Royalties shall accrue until after the Royalty Date.

(License Agreement, § 3.2). "Net Selling Price" is defined as "the invoice price of the Licensed Products, less the follow-

ing, according to the customary practice of Cordis, discounts allowed to distributors, discounts for clinical testing units (regardless of where the units are made or used), refunds, returns, the costs of replacement or credit freight, postage, shipping, insurance and other shipping charges, customs, duties and other governmental charges and import, use and sales tax)." (License Agreement, § 1 1.3). And, " commercialization d ate" is "the d ate o n which the first commercial sale of any of the Licensed Products is made, after receipt of governmental approval to market the Licensed Products on an unrestricted basis." (License Agreement, § 1.1.4).

The royalties would be paid as follows:

> On the first day of the month after the expiration of three months after the Royalty Date, and each three months thereafter, Cordis shall determine the Net Selling Price of all Licensed Products (i) sold, or (ii) used in a medical procedure by Cordis, its Affiliates, and Sublicensees during the immediately preceding three month period and, within 15 days after the expiration of each such three month period, Cordis shall pay AGR the Running Royalty, if any. If no Running Royalties are due, Cordis shall send a written notice indicating the same to Licensor [AGR].

(License Agreement, § 4.2). Significantly, "[t]he obligation to pay a Running Royalty shall be imposed **only** once with respect to the same Licensed Products." (License Agreement, § 4.3) (emphasis added). Moreover, "[i]n the event that any claim of any of the Patents shall be declared invalid in any court of competent jurisdiction and in which no further appeal is available or is taken, no future royalty, Running Royalty or Advance payments shall be required in respect of such invalid claim." (License Agreement, § 4.4).

Among the warranties and representations made, AGR agreed that it knew of no entity or person who was infringing upon the rights of AGR in or to the Rockey Patents. (License Agreement, § 6.5). A merger or integration clause provides that the "License Agreement supersedes and replaces all previous agreements between the parties, and sets forth all of the agreements and understanding made between the parties hereto regarding the subject matter hereof." (License Agreement, § 14.1). The parties also agreed that the Agreement would be governed by Florida law. (License Agreement, § 14.3). Paragraph 14.9 of the License Agreement provides that "Cordis **may** attempt to obtain a term extension for the Patents if Cordis determines that the likely term extension will result in an additional a mount of Running Royalties which exceeds the reasonable cost of obtaining such extension," and "Cordis shall provide Licensor [AGR] with information necessary to obtain any available term extension for the Patents from Patent and Trademark Office as a result of governmental regulatory approval." (emphasis added). The License Agreement was to finish at the end of the term for the last patent to expire of any of the Rockey Patents, (License Agreement, § 7.1), and has never been terminated pursuant to the termination provisions of paragraph 7.2.

Pursuant to paragraph 3.1 of the License Agreement, Cordis paid AGR the sum of $2 million as an advance payment of pre-paid royalties. Approximately six months after execution of the License Agreement, on November 6, 1995, Cordis agreed to be acquired by J & J, and the merger was completed in February 1996. Since then, Cordis has continued to sell balloon-expandable metal stents. Cordis has not paid the Running Royalty to AGR for the sale of any products, including its sales of Palmaz and Palmaz-Schatz stents. At all times since May 15, 1995, the date the License Agreement was executed, AGR has been the owner of the Rockey Patents. Neither AGR nor Cordis has filed an application to ex-

tend the term of any of the Rockey Patents under 35 U.S.C. § 156.

E. EXPERT TESTIMONY

The parties have identified experts, produced expert reports and conducted expert discovery. On June 9, 2003, AGR produced two liability expert reports from Dr. Edward F. Leonard ("Dr. Leonard") and George P. Widas ("Widas"). As set forth in the reports, the experts conducted an element-by-element analysis of claim 2 of the '1,653 Patent. In each instance where the experts addressed the respective claim elements, they did not limit their opinions to literal infringement.

Dr. Leonard has examined the Rockey Patents and various balloon-expandable stents sold by Cordis. Based upon his review of these materials, expertise in biomechanical engineering, and first-hand knowledge from working with balloon-expandable stents, Dr. Leonard has concluded that the Cordis stents infringe upon claim 2 of the '1,653 Patent. Referring to Cordis' stents, Dr. Leonard concludes:

> 30. Reviewing the Cordis documents, products and product inserts, it is clear that the Accused product is to be used for introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve or stent encircling the balloon on its end into a vessel at a point remote from the area to be treated. For instance, the coronary stent is inserted in the femoral artery which is remote from the coronary arteries, which is the area to be treated.
>
> 31. The device and its instructions further provide for manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated.
>
> 32. The instructions clearly provide for inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner

where the sleeve surrounding the balloon is radially expanded towards the wall of the vessel. A review of the Accused Product clearly provides for radial expansion of the sleeve or stent through the inflation of the balloon.

33. Further, the Cordis Accused Products have a material in the sleeve which increases in rigidity after expansion of the balloon. That is, the stainless steel utilized in the stent or sleeve is internally strengthened by plastic deformation within each of its elements. It is also strengthened in its entirety by reorientation of its elements with respect to each other from an initial, predominantly axial orientation to a final, more circumferential position. This reorientation stiffens the stent and enables it to resist compressive stresses that tend to collapse it. Both changes result in an increase in rigidity over a period of time that includes the time during which the stent is freely expanding and an interval of time thereafter when the stent is accommodating to the blood vessel wall.

34. Subsequently, the balloon is removed and the catheter is removed from the vessel to allow the sleeve and stent to remain in place in the area to be treated.

35. It is my opinion to a reasonable degree of engineering certainty that based upon my review of the Accused Products and the method by which those products are specified for their use as described in the instructions provided, and with the devices furnished for their placement, that the accused device meets every limitation of claim 2 of the '1,653 Patent.

(Leonard Expert Report, at ¶¶ 30-35). Dr. Leonard's theory has three parts: (1) the geometric orientation of the tiny metal bars in Cordis' stents somehow changes after balloon expansion, in a way that increases rigidity of the stent, (2) the

stainless steel in Cordis' stents undergoes plastic deformation for a brief period of time after the balloon is expanded, and (3) the stent increases in rigidity due to a supposed interaction between the stent and the wall of the artery during the 20-60 seconds that the balloon is maintained in an expanded condition before being deflated and withdrawn.

In his report, Mr. Widas also concludes that each of the elements of claim 2 of the '1,653 Patent can be found in the balloon-expandable stents sold by Cordis. Among the many opinions expressed by Mr. Widas, he concludes that the Cordis stents increase in rigidity after expansion of the balloon. (Widas Expert Report, ¶ 32).

Mr. Widas and Dr. Leonard hypothesize that after expansion of the balloon, the Cordis stents increase in rigidity to an infinitesimally small extent - which they have not even tried to measure. (Widas Expert Report, ¶¶ 32-33; Widas Depo., p. 156-57; Leonard Depo., 194:12-23). Mr. Widas' theory is that Cordis' stents undergo a phenomenon called "strain hardening" for an infinitesimally small period of time after the balloon stops expanding. According to Mr. Widas, this small amount of strain hardening results in a tiny increase in rigidity after expansion of the balloon.

Following AGR's production of its expert reports, Cordis was provided with the opportunity to depose Mr. Widas and Dr. Leonard. During those depositions, Cordis' counsel inquired regarding whether the experts had any opinion regarding the legal issue of the "doctrine of equivalents." Neither witness was prepared to offer opinions. However, throughout the course of the depositions, it was clear that both witnesses had included in their technical analyses and opinions, a recognition that the Cordis stents function in substantially the same way to achieve substantially the same result as the device set forth in the specification of the '1,653 Patent.

For example, Dr. Leonard testified to the following:

Q. Do you have an opinion on whether or not the Cordis products infringe the claims if they do not have exactly what is called for in the claims?

A. Yes, I do. I think that if they have substantially, what is called for in the claims, or - that is sufficient.

Q. And how would you go about determining that?

A. Functionally, to a large degree. That is to say that using the definition of a balloon, as an example I know what a balloon does and if something accomplished the same thing that a balloon did, and had a physical resemblance to a balloon, and could replace the balloon, but with no major difference in function, I would say that that was - that that was still covered by the original patent and it was infringing if you made something that did that.

(Leonard Depo., 68:14-25). In fact, Cordis was provided with additional notice that Dr. Leonard's opinions were not limited to literal infringement when Cordis' counsel asked the following questions:

Q. You gave a certain understanding of the law about infringement. I want to know in that opinion, understanding was, that if it is not exactly what is in the claim there could still be an infringement. I want to know where that understanding of the law came from.

A. I drew it, I think in part from what I thought was logical and from statements of the kind that you see in the patent. For example, the invention is not restricted the Slavin [sic] limitation of each and every detail set forth.

> Devices may be provided which change, eliminate and add certain specific details without departing from the scope of the invention.
>
> Q. As a legal matter, do you know what effect that sentence has, if any, on the rights of the patent?
>
> A. No, I do not.

(Leonard Depo., 70:8-71:2).

The same is true with respect to the Widas deposition. During his deposition, Mr. Widas testified:

> Q. In your work in patent cases have you ever heard of the doctrine of equivalents?
>
> A. I have heard those words.
>
> Q. Do you have any opinion on whether or not Cordis infringes claim 2 of the Rockey patent under the doctrine of equivalents?
>
> A. You would have to explain it to me. I have heard the term, but I wouldn't know the significance of it in that context.

(Widas Depo., 56:8-19). Cordis' counsel did not explain the doctrine of equivalents, nor present an engineering question. Nevertheless, less than two pages later, the witness testified that his opinions regarding infringement were not based upon an "exact" reading of the claim:

> Q. So if the Cordis device lacks one of the elements of the claim, then it does not infringe; is that correct?
>
> A. Yes.
>
> Q. Do you have any opinions on whether or not Cordis infringes the Rockey 2 patent if somebody determines that Cordis does not have exactly one of the elements?

A. Your word "exactly" is the only one that causes me hesitation.

Q. Okay.

A. I don't know and it is my understanding that it doesn't have to be exactly. That it has to be what it says.

(Widas Depo., 58:14; 59:6). Mr. Widas was offered as an expert on one element of claim 2. That is, Mr. Widas' opinion was limited to the material in the sleeve which increases in rigidity after expansion of the balloon due to plastic deformation (Widas Expert Report, ¶¶ 32-33). Counsel did not follow up with Mr. Widas regarding whether or not Widas had an opinion as to whether the sole element which was the subject of his report (*i. e.*, "providing in the sleeve a material which increases in rigidity after expansion of the balloon"), had to be found exactly in the accused device

Cordis has produced liability expert witness reports from Dr. Campbell Laird ("Dr. Laird") and interventional cardiologist Dr. Joseph A. Puma ("Dr. Puma"). Laird's report provides testimony with respect to the reverse doctrine of equivalents. (Laird Expert Report, p. 16-17). Thus, Cordis has presented expert testimony directly relating to whether the accused device functions in substantially the same way to achieve substantially the same result as the invention disclosed in the specification of the '1,653 Patent.

On July 9, 2002, AGR produced the rebuttal report of David P. Pope ("Dr. Pope"). The Pope Report addresses a number of issues raised by Dr. Laird, including Dr. Laird's testimony regarding the reverse doctrine of equivalents. Following the production of that report, on July 11, 2003, Cordis deposed Dr. Pope. During that deposition, Dr. Pope provided the actual bases of his analysis regarding infringement in general, and specifically in connection with his opinion regarding infringement under the doctrine of equivalents. Dr. Pope testi-

fied regarding insubstantial differences between a stent made of metal and one made of polymer in terms of the way each increases in rigidity after expansion of the balloon. (Deposition of David P. Pope ("Pope Depo."), 78:16; 79:11). Dr. Pope opined that it is the expansion of the balloon that causes the stent to expand. Once the balloon stops expanding, so does the stent. (Pope Depo., 99:10-21). Since the stent only undergoes strain hardening when it is undergoing plastic deformation and being expanded, it cannot possibly undergo strain hardening after the balloon stops expanding. (Pope Depo., 124-125).

Dr. Pope expressly testified regarding the factual bases for his infringement analysis under the doctrine of equivalents:

> A. In the case of the metallic stent, the plastic deformation serves precisely the same function as the polymerization. That is to say, when the polymeric material is in its unmixed state, it has a resistance to change of essentially zero. That is to say, it's a liquid, so it deforms very easily. Then when it polymerizes and it becomes elastomeric, it becomes very resistant to shrinkage, and so you are comparing the resistance to shrinkage of the polymerized material to the liquid.
>
> In the case of the plastic material, you're comparing the resistance of expansion of the plastically deforming material to the contraction of the now elastically deforming material, and while that difference isn't the difference between a liquid and a solid, it is a change of resistance of some factors of hundred and therefore is a huge difference in the rigidity of the two.

(Pope Depo., 78:16; 79:11). Thus, AGR's experts have opined that a stent made of stainless steel, which is plastically deformed during expansion, functions in substantially the same way to achieve substantially the same result as a stent

made by a polymer which undergoes polymerization and hardening upon expansion. In direct contrast to the opinions provided by AGR's experts on the doctrine of equivalents, Dr. Laird has provided testimony that the accused Cordis device does not function in substantially the same way to achieve substantially the same result.

On August 7, 2003, AGR filed its response to Cordis' Motion for Summary Judgment. Among the exhibits submitted in support of AGR's Response were declarations of AGR's three experts. These declarations provide additional analysis of infringement under the doctrine of equivalents.

AGR later submitted a Supplemental Expert Report of Dr. Leonard. The Supplemental Report further elaborates on Dr. Leonard's opinions on infringement under the doctrine of equivalents. Here, Dr. Leonard testifies that a polymer stent functions in substantially the same way to achieve substantially the same result as stent made of 316L stainless steel in that (1) "Both can be made so small so as to be able to be inserted into the body at a point remote from the area to be treated;" (2) both are "flexible and can be manipulated to the area to be treated;" (3) "both can be expanded to varying sizes by a balloon mounted catheter;" (4) "both are made to increase in rigidity during and after expansion of the balloon;" (5) "both radically expand towards the wall of the vessel when the balloon is inflated;" (6) "both increase in rigidity while the balloon is maintained in an expanded condition;" and (7) "both remain in place in the area to be treated after the balloon and catheter are removed from the vessel." (Leonard Supplemental Report, ¶¶ 7-12).

Additionally, in his Supplemental Report, Dr. Leonard responded to opinions of Cordis' experts, Drs. Laird and Puma, that Dr. Rockey's Patent Application Serial No. 912,010 does not disclose the use of a material which increases in rigidity after expansion of the balloon. Dr. Leonard reviewed Dr. Rockey's applications concludes that both the '010 Applica-

tion and the '989 Application disclosed to one skilled in the art all of the limitations found in claim 2 of the '1,653 Patent. (Leonard Supplemental Report, ¶ 17).

AGR has also produced the expert report of attorney William H. Murray. In his report, Mr. Murray relies upon Dr. Leonard's Supplemental Report. AGR's stated purpose for Mr. Murray's testimony is to explain to the jury that, based upon his review of the Patent file history, as well as his reliance upon a person skilled in the art, the Rockey Patents are entitled to an effective filing date of June 1978. AGR intends to have Mr. Murray testify regarding the effect of the patent application process which resulted in the '1,653 Patent.

F. QUALIFICATIONS OF THE EXPERTS

Dr. Leonard is a chemical and biomedical engineer. Dr. Leonard obtained his undergraduate degree in 1953 from the Massachusetts Institute of Technology, and later obtained his masters and doctorate in chemical engineering from the University of Pennsylvania. Since 1968, Dr. Leonard has been a professor at Columbia University, where he currently teaches chemical and biomedical engineering. Dr. Leonard has been involved in biomechanical engineering for approximately 56 years. Dr. Leonard holds a patent for a catheter device. He has also conducted research with stents, including their placement and analysis after removal. For approximately eight years, part of Dr. Leonard's work included consulting for Interventional Technologies, now part of Boston Scientific, Inc. With regard to balloon-expandable stents, Dr. Leonard's experience includes using balloon-expandable stents in research; helping design stents for Interventional Technologies; researching the interaction between stents and vessel walls; providing consulting services on a variety of stent issues involving fluid mechanics, tissue reactions and controlled release theory; calculating and examining the ability of stents to withstand compressive stresses and having many discussions with interventional cardiologists regarding stenting procedures.

Mr. Widas is a professional engineer with over 30 years of experience, including advanced engineering studies in biomechanics. He has received professional training in the areas of physics, mechanics, vectors, deformable bodies and material behavior. He is a consultant in the application of the physical sciences and principles of safety engineering to event analysis and reconstruction.

Dr. Pope and Dr. Laird are materials scientists, or metallurgists. Dr. Laird has a doctorate in physics, chemistry and mathematics, and has been practicing in the field of materials science and engineering for 44 years. He is a professor in this subject at the University of Pennsylvania. Dr. Pope is also a professor of materials science and engineering at the University of Pennsylvania, and has a doctorate in materials science. Both Drs. Pope and Laird are experts in the properties of various materials, including stainless steel.

Dr. Puma, an interventional cardiologist, has been using stents for over a decade and performs 200-400 interventional procedures a year. Dr. Puma participated in one of two major clinical trials that showed that the Palmaz-Schatz stent significantly reduced the rate of restenosis[3] as compared to balloon angioplasty. He is an Associate Consulting Professor of Medicine (Cardiology) at Duke University Medical Center. Dr. Puma is familiar with the treatment of ischemic heart disease from surgical coronary artery bypass grafting to balloon angioplasty, to the current treatment, stenting. He is also familiar with how stents became the standard of care for treating ischemic heart disease and how interventional cardiologists use Cordis stents.

Dr. Puma is familiar with stent designs, having used stents for over a decade. He has reviewed marketing literature de-

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[3] Restenosis is a narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or a stent procedure, has already taken place.

scribing stents and has examined stents in practice. Dr. Puma is skilled in using a catheter and balloon and removing them from a vessel. Dr. Puma uses balloons mounted on catheters and removes them from the vessel in his stenting procedures. He has expertise in what happens to stainless steel upon expansion.

William H. Murray is a registered patent attorney in the law firm of Duane Morris, LLP, in Philadelphia, with 29 years of experience in the field of intellectual property. He has prepared or supervised the preparation of hundreds of United States patent applications. He has testified as a patent expert in three judicial proceedings.

Cordis does not intend to offer any expert or opinion testimony by Dr. Palmaz at trial. If permitted to testify, Dr. Palmaz would testify as a fact witness. Dr. Palmaz would testify about his inventions disclosed in U.S. Patent Nos. 4,833,665 and 4,739,762. He would discuss his initial conception of the idea, his animal experiments and implants starting in 1984, and ultimately his collaboration with J & J to commercialize the invention.

II. PROCEDURAL BACKGROUND

AGR brought this action against Cordis in state court on July 1, 2002. Count I is for breach of contract based on Cordis' failure to pay the Running Royalty under the License Agreement, despite AGR's written request for payment. AGR alleges that Cordis was obligated under the License Agreement to extend the term of the Rockey Patents. AGR claims that Cordis' failure to pay the Running Royalty, and its failure to extend the life of the Rockey Patents, constitute material breaches of the License Agreement.

In Count II for breach of the duty to exploit, AGR claims that the exclusive licensing provision of the License Agreement subjects Cordis to an express duty to commercially exploit the technology covered by the Rockey Patents. In addi-

tion, the exclusive licensing provision allegedly subjects Cordis to an implied duty to use its best efforts to commercially exploit the inventions in the Rockey Patents.

Count III is for breach of the duty of good faith and fair dealing in connection with the License Agreement. AGR relies on the language in the Agreement that Cordis "may" attempt to obtain a term extension for the Rockey Patents. Such an extension would have resulted in a longer period of time during which Cordis would have been obligated to continue to pay the Running Royalty. AGR alleges that Cordis did not seek to extend the life of the Rockey Patents in an effort to avoid its continuing obligation to pay AGR the Running Royalty based on the sale of Licensed Products by Cordis and its affiliates. Cordis' failure to extend the life of the Rockey Patents, it is alleged, constitutes a breach not only of the License Agreement, but also of Cordis' duty of good faith and fair dealing. AGR seeks declaratory relief and damages for lost revenues, lost past royalties and lost future royalties on all counts.

Cordis maintains that Count I fails because Cordis' stents are not the medical sleeves that Dr. Rockey invented and that AGR licensed to Cordis. Cordis claims that its stents are an entirely different kind of device; they are based on inventions by Dr. Palmaz and Dr. Schatz, which were independently licensed to Cordis. Cordis raises the following affirmative defenses in its Answer to the Complaint: (1) the Complaint fails to state a claim upon which relief may be granted; (2) AGR's claims are barred under the doctrines of laches, waiver and estoppel; (3) AGR's claims are barred in whole or in part under the statute of limitations; (4) neither Cordis nor its "affiliates" (as that term is used in the License Agreement) makes, uses, sells or offers for sale, or has ever made, used, sold or offered for sale, any product that is covered by the Rockey Patents; (5) if any claim of the Rockey Patents is construed so as to cover any of the Cordis balloon-expandable stent products, then any such claim is invalid under 35 U.S.C. § 102,

103 and/or 112; and (6) if any of Cordis' balloon-expandable stent products literally meet the limitations of any of the claims of the Rockey Patents, then any such products do not infringe the Rockey Patents under the reverse doctrine of equivalents. Cordis admits to the following: (1) Cordis has not paid the Running Royalty to AGR (because Cordis does not owe any Running Royalty to AGR); (2) in or about early 1996, Cordis became a J & J company; (3) Cordis sells a product called the Palmaz Balloon-Expandable Stent; (4) Cordis has not extended the life of any of the Rockey Patents; (5) Cordis' obligation to pay a Running Royalty would not begin until after Cordis had sold in excess of $20,000,000 worth of products covered by the Rocket Patents; and (6) the PTO issued the Rockey Patents referenced in the Complaint.

Cordis filed a Notice of Removal pursuant to 28 U.S.C. § § 1441 and 1446, asserting that this Court had jurisdiction under 28 U.S.C. § 1338 because Count I necessarily depends on the resolution of a substantial question of federal patent law. In its Motion to Remand, AGR argued that Counts II and III presented alternative legal theories for the breach of contract claim under which resolution of a patent law issue is not essential. Cordis responded that in order to prevail on its claim for royalties under Count I, AGR had to prove that Cordis' stents are Licensed Products, those being stents covered by at least one claim of the Rockey Patents and, accordingly, that AGR had to prove the stents would infringe on one of the Rockey Patents but for Cordis' license to use those Patents.

AGR's Motion to Remand was denied by Order dated November 12, 2002 (D.E. 26). The Court[4] found that all of AGR's claims arise out of or relate to the parties' License Agreement. Noting that the "Court's task here is to determine

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[4] That Order was entered by the Honorable Paul C. Huck, United States District Court Judge for the Southern District of Florida, before the case was transferred to the undersigned.

whether any one of the Rockey, Inc,'s claims depends on the resolution of a substantial issue of federal patent law," the Order further stated:

> Even though Rockey, Inc. denominates Count I as a simple state law breach of License Agreement claim, it seems obvious that **for Rockey, Inc. to prevail on that claim, Rockey, Inc. will have to prove that the stents sold by Cordis are covered by Dr. Rockey's patents. Stated in patent terminology, Rockey, Inc. must prove that the stents resulted from Cordis practicing Dr. Rockey's patent, as Cordis was entitled to do under the License Agreement.** Rockey, Inc. would have to read the patent onto the stents, which Rockey, Inc. contends are Licensed Products, in order to prove its claim for royalties .... The Court concludes that because one of Rockey, Inc.'s three claims, Count I, requires the resolution of a substantial question of federal patent law, the Court has 'arising under' jurisdiction pursuant to § 1338(a).

Id. (emphasis added). With respect to AGR's argument that Counts II and III did not involve a federal patent law issue, and were alternative to Count I, the Court rejected AGR's contention, finding Counts II and III to be not alternative theories, but rather additional claims, independent of AGR's breach of contract claim for royalties resulting from Cordis' sale of Licensed Products.

The Order suggested that interlocutory review by the United States Court of Appeals for the Federal Circuit under 28 U.S.C. § § 1292(b) and (c) may be appropriate because the Order "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation" in a patent infringement case over which the Federal Circuit would have exclusive jurisdiction of appeals under 28 U.S.C. § 1295. Ac-

cordingly, AGR filed a petition for permission to appeal the November 12, 2002 Order with the Federal Circuit. The Federal Circuit exercised its discretion in denying AGR permission to appeal, noting that "[i]t appears that the parties agreed that the first count, concerning breach of the license agreement, arose under the patent laws, such that a federal district court would have jurisdiction over that count." (D.E. 36).

The parties have filed the various motions *in Limine* listed above. Cordis has also filed a motion for summary judgment, and a separate motion for claim construction of the terms of the ' 1,653 Patent in lieu of a summary judgment favorable to Cordis.

III. LEGAL DISCUSSION

A. AGR'S MOTIONS *IN LIMINE*

1. AGR's Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents

AGR seeks to preclude the introduction at trial of any evidence regarding the validity of the three Rockey Patents covered by the License Agreement. AGR argues that, based on the License Agreement, the validity of the claims of the '1,653 Patent, or of any of the other two Rockey Patents, is not relevant to any issue before the jury. AGR contends that the validity of the Rockey Patents has no effect upon Cordis' obligations to pay **past** royalties under the License Agreement. In this regard, paragraph 4.4 of the License Agreement provides:

> In the event that any claim of the Patents shall be **declared** invalid in any court of competent jurisdiction and in which no further appeal is available or is taken, no **future** royalty, Running Royalty or Advance payment shall be required in respect of such invalid claim.

(emphasis added). AGR also argues that "there is no cause of action which could in any way support a **declaration** of inva-

lidity of any claim of the Rockey Patents." (Motion, p. 4) (emphasis added).

Cordis' position is that claim 2 of the Rockey '1,653 Patent does not cover Cordis' stents, and that if the claim were construed so broadly so as to reach Cordis' stents, then the claim would be invalid under 35 U.S.C. §§ 102(a) and 102(g), because Dr. Palmaz invented the subject matter first. Cordis further argues that invalidity would negate AGR's claim for Running Royalties because the License Agreement provides that Cordis owes Running Royalties only on "Licensed Products," which are defined in the Agreement as products that are "covered by" any claim of the Rockey Patents. According to Cordis, this language requires a licensor to pay royalties only on products that would infringe the licensed Patents under federal patent law.

The plain language of paragraph 4.4 of the License Agreement does not limit the effect of a finding of invalidity to **future** royalties. Rather, the Agreement limits liability for future royalties **as well as** Running Royalties and the Advance Payment. This language makes clear that if any claim of the Rockey Patents is found invalid, then Cordis is not required to pay "future royalties," or "Running Royalties," or "Advance Payment." Accordingly, a finding that claim 2 of the '1,653 Patent is invalid would provide a complete defense to AGR's claim for Running Royalty payments.

The invalidity of claim 2 is not just a defense under the Agreement, and therefore a relevant inquiry, it is also a defense as a matter of substantive patent law. Cordis has specifically pled invalidity of the Rockey Patents under 35 U.S.C. §§ 102, 103, and/or 112 as an affirmative defense. Accordingly, experts offered by both parties have opined on the validity of the Rockey Patents. Under 35 U.S.C. § 282, invalidity may be raised as an affirmative defense in any "action involving ... infringement." *See also Stairmaster Sports/Medical Prod, Inc. v. Groupe Procycle, Inc.*, 182

F.R.D. 117,118-19 (D. Del. 1998); *Cornwall v. U.S. Constr. Mfg., Inc., et al.*, 800 F.2d 250, 252-53 (Fed. Cir. 1986) (citing 35U. S.C. § 282). Moreover, Section 282 provides a clear statutory authority for a **declaration** of invalidity. *Constant v. Advances Micro-Devices, Inc.*, 848 F.2d 1560, 1563-64 (Fed. Cir. 1988) ("[35 U.S.C. § 282] permits the federal courts to adjudicate the validity of patents when invalidity is raised as an affirmative defense in infringement suits.").

And it is the law of this case that AGR's claim for Running Royalties is a claim involving infringement. The Order denying AGR's Motion to Remand states that to prevail on its claim for Running Royalties, AGR must show that "the stents sold by Cordis would have infringed" the Rockey Patents but for the License Agreement. *See also Interspiro USA, Inc. v. Figgie Int'l, Inc.*, 18 F.3d 927, 930 (Fed. Cir. 1994) (finding that when an agreement requires a party to pay royalties on sales "covered by" a patent, the issue of whether the party must pay a royalty "turns on whether the [accused product] infringes [that] patent"). Thus, as this is a case "involving infringement," invalidity of the '1,653 Patent is available as a defense.

AGR misinterprets the November 12, 2002 Order in suggesting that it establishes only that federal law provides the basis for jurisdiction but need not be applied to Count I, and rather that state law controls the breach of contract count. This is not the clear holding. The ruling was based on the application of **federal** law to the issue of patent infringement that is necessary to the resolution of Count I, and to which state law cannot provide the grounds for decision. *See, e.g., 3D Sys., Inc. v. Aarotech Laboratories, Inc.*, 160 F.3d 1373, 1379 (Fed. Cir. 1998) (holding that a determination on patent infringement was an issue governed solely by federal law, not state contract law because "[d]efining the contours of the tort of [patent] infringement, which exists solely by virtue of federal statute, entails the construction of the federal statute [and

federal common law] and not a state's common or statutory law").[5]

The Court is bound by the law-of-the-case doctrine. The Supreme Court has described the law-of-the-case doctrine as follows:

> A court has the power to revisit prior decisions of its own court or of a coordinate court in any circumstances, although as a rule courts should be loath to do so in the absence of extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'

Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 817 (1988). The Eleventh Circuit has clarified: "Courts must rarely invoke the 'clear error' exception, less the exception swallow the rule." *Jenkins Brick Co. v. Bremer*, 321 F.3d 1366, 1370 (11th Cir. 2003); *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000). AGR does not argue, nor does the record reflect, that the November 12, 2002 Order was erroneous, let alone "clearly erroneous." Because the jury will be asked to consider patent infringement on Count I, and invalidity of the '1,653 Patent is a defense that is available to Cordis on this claim, evidence regarding the validity of the Rockey Patents[6] is relevant and admissible.

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[5] Decisions by the U.S. Court of Appeals for the Federal Circuit provide controlling authority on the aspects of this case that are unique to patent law. *Lummus Indus. v. D.M & E. Corp.*, 862 F.2d 267, 270 (Fed. Cir. 1988). Decisions by the Eleventh Circuit govern issues that are not unique to patent law, *see id.*, and Florida provides the applicable state law because the parties chose Florida law to govern their Agreement. (License Agreement, § 14.3).

[6] Because AGR seeks application of the earlier filing date of one of the other Rockey Patents to the '1,653 Patent based on the disclosure of the same invention, evidence regarding validity of **all three Rockey Patents** is relevant and may be introduced at trial.

2. AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony, and Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985 for Claim 2 of the '1,653 Patent

AGR moves to preclude the introduction at trial of any evidence concerning Dr. Palmaz's alleged conception of the Palmaz stent prior to 1980, even though his first patent application date concerning this device is November 7, 1985. There is not only conflicting evidence as to Dr. Palmaz's conception date,[7] but there is also conflicting expert evidence as to what priority date should apply to claim 2 of the Rockey '1,653 Patent. The application that resulted in the '1,653 Patent was filed on February 19, 1985. AGR's theory is that a 1978 priority date applies to claim 2 of the '1,653 Patent because Dr. Rockey filed a different patent application on June 2, 1978, and the '010 Application disclosed the same invention described in claim 2. Cordis argues that AGR is not entitled to the earlier filing date because AGR cannot show that the '010 Application filed in 1978 disclosed each and every limitation of claim 2. However, Cordis admits that whether or not AGR is entitled to only a 1985 priority date based on a limitation-by-limitation analysis is a "disputed issue" for the jury.

Because invalidity of the Rockey '1,653 Patent is an affirmative defense, and because the determination of who is the prior inventor of the technology is relevant to the issue of validity, it will be the jury's function to weigh the conflicting evidence to determine what priority dates should be applied to the Palmaz invention and the Rockey invention. The cross-motions are therefore denied.

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[7] AGR concedes that there is conflicting evidence on this issue in its Reply brief, asserting that "[a]lthough unclear, it appears that Dr. Palmaz allegedly conceived of his invention **sometime between 1978 and 1984.**" (Reply, p. 1) (emphasis added).

3. AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph Puma

AGR moves *in Limine* to preclude the expert opinion testimony of Drs. Laird and Puma at trial. AGR maintains that these expert witnesses offered by Cordis lack experience in the design, study, evaluation and testing of medical devices, including the stent technology at issue.

To the contrary, the record shows that Drs. Laird and Puma are sufficiently skilled in the relevant art so that their testimony may assist the jury in understanding the evidence relating to the devices developed by Drs. Rockey and Palmaz. As a materials scientist, Dr. Laird is an expert with regard to the properties of various materials, including stainless steel, which is the material contained in the Cordis stents. (Laird Expert Report, p. 1-2). Indeed, he states that the focus of his "research and professional activities has been fracture and deformation, especially fatigue and cyclic deformation, and the interrelationship of these phenomena with static fracture and deformation." (Laird Expert Report, p. 2).

Dr. Puma has been using balloon-expandable stents such as the Palmaz-Schatz stent for almost a decade. He conducts at least 200 to 400 procedures involving stents every year. (Puma Expert Report, p. 1). Dr. Puma has even participated in a major clinical trial conducted in the United States to assess the effectiveness of the stenting procedure using the Palmaz-Schatz stent in comparison with another treatment. (Puma Expert Report, p. 9).

Dr. Laird will, therefore, be permitted to testify at trial regarding general principles of material science. Dr. Puma will be permitted to testify regarding stent technology and design, including that of the Cordis stents, and stenting procedures used to treat heart disease. Additionally, both Drs. Laird and Puma, based on their particular experience in the relevant art, will be permitted to offer opinions on the validity of the

Rockey '1,653 Patent, and on infringement of the terms of claim 2 of the '1,653 Patent, as those terms are construed in this Order.

4. AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony

The parties agree that fact witnesses should not be permitted to testify regarding undisclosed expert or opinion testimony. Accordingly, the parties shall not offer any undisclosed expert or opinion testimony through their fact witnesses, or elicit such testimony from the opposing party's fact witnesses.

5. AGR's Motion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection

AGR seeks to exclude evidence concerning the development by J & J of the Palmaz balloon-expandable stent subsequently sold by Cordis, and the award of United States patents to Dr. Palmaz covering this accused device. Contrary to AGR's assertions, such evidence is relevant to several issues in this case, including but not limited to, the validity of the Rockey '1,653 Patent and the "equivalence" of the Rockey sleeve and the Palmaz stent under the doctrine of equivalents. Courts have found that patentability of an accused product is **relevant** in cases involving a determination of infringement under the doctrine of equivalents. *See, e.g., Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*, 344 F.3d 1226, 1233 (Fed. Cir. 2003) ("**this fact [a patent covering the accused product] may be weighed by the district court**, particularly if there is an issue of 'insubstantial' change with respect to equivalency") (emphasis added); *National Presto Indus., Inc. v. West Bend Co., Inc.*, 76 F.3d 1185, 1191-92 (Fed. Cir. 1996) ("Whether a modified device is within the scope of the prior patent, literally or by equivalency, depends on the particular facts. **The fact of separate patentability is relevant, and is entitled to due weight.**") (citing *Atlas Powder Co. v.*

E.L. du Pont de Nemours & Co., 750 F.2d 1569, 1580-81 (Fed. Cir. 1984)) (emphasis added); *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 (Fed. Cir. 1993); *Magnesystems, Inc. v. Nikken, Inc.*, 933 F. Supp. 944, 952 (C.D. Cal. 1996). Nevertheless, "[t]he grant of a separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent." *National Presto*, 76 F.3d at 1191-92 (citation omitted). Thus, the separate patents issued to Dr. Palmaz and other inventors are relevant, although not dispositive of the determination of infringement.[8]

B. CORDIS' MOTIONS *IN LIMINE*

1. Cordis' Motion *in Limine* to Exclude Parol Evidence

Cordis seeks to preclude AGR from introducing parol evidence of the parties' intent when they entered into the License Agreement. For example,

> Cordis seeks to preclude admissions made by Cordis representatives to Gina Rockey that AGR's patents 'were very broad,' that the License Agreement would cover both metal and polymer stents, and that Cordis projected AGR's royalties to be in excess of $100,000,000 under the License Agreement.

(AGR's Response, p. 6). It is AGR's position that the License Agreement is clear and unambiguous in that it provides that Cordis is liable to AGR for royalty payments based on the sale of any stents that incorporate "in whole or in part" any of the improvements set forth in the Rockey Patents. However, AGR maintains that if the License Agreement found to be

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[8] Moreover, it is not readily apparent that admission of evidence on the development of and the patentability of the Palmaz stents and other stents sold by Cordis would create unfair prejudice to AGR or jury confusion.

ambiguous, parol evidence is necessary to clarify an ambiguity. Moreover, and in the alternative, AGR relies on the fraudulent inducement exception to the parol evidence rule under Florida law, which permits parol evidence of a contemporaneous oral agreement to "vary, change, or reform" a written agreement, but not directly contract it. (AGR's Response, p. 5-6 (citing *Ungerleider v. Gordon*, 214 F.3d 1279, 1282 (11th Cir. 2000))); *see Mallard v. Ewing*, 121 Fla. 654, 664 (1935).

In response to AGR's first argument, Cordis maintains that evidence regarding the parties' intent and/or any pre-contractual oral agreements is irrelevant and inadmissible because there is no ambiguity in the License Agreement concerning Cordis' obligations to pay royalties. The License Agreement requires Cordis to pay royalties **only** on "Licensed Products," and it explicitly defines "Licensed Products" as products that are "covered by any claim of the [Rockey] Patents." This language requires Cordis to pay royalties **only** on products that would "infringe the [licensed] patent[s]" under federal patent law. Indeed, this is precisely the interpretation of the License Agreement adopted in the November 12, 2002 Order.

Two provisions of the License Agreement address Cordis' obligation to pay royalties: paragraphs 1.1.2 and 3.2. Paragraph 3.2 states that "Cordis shall pay to Licensor a running royalty" on sales of "all Licensed Products." "Licensed Products," in turn, are defined in paragraph 1.1.2 as products that are "covered by any claim of the Rockey Patents." The License Agreement obligates Cordis to pay royalties only on products that infringe a claim of the Rockey Patents.

AGR cites to paragraph 2.1 of the License Agreement, which grants Cordis "an exclusive, world-wide license to manufacture, have manufactured, use and sell devices or products incorporating **in whole or in part** any and all of the inventions and improvements disclosed or claimed in the Pat-

ents." (emphasis added). AGR presumably relies on this provision to support its claim that Cordis agreed to pay royalties on products that use only **a part** of the invention disclosed or claimed in the Rockey Patents. This argument is unavailing. Paragraph 2.1 has no bearing on Cordis' obligation to pay royalties; rather, it defines the scope of the license rights granted to Cordis under the Agreement. Therefore, there is no conflict between paragraph 2.1 and paragraphs 1.1.2 and 3.2, and no ambiguity in the License Agreement is created by a comparison of these provisions.

AGR's reliance on *Gjerlov v. Schuyler Laboratories, Inc.*, 131 F.3d 1016 (Fed. Cir. 1997) is misplaced. In that case, the Federal Circuit applied Iowa law to a question of interpretation of a settlement agreement reached in a patent infringement action. The Court held that the issue of contract interpretation was not governed by federal patent law, but by state contract law, in an action alleging breach of the contract, and the Court considered parol evidence to resolve an ambiguity in the contract. *Id.* at 1020-22. The ambiguous terms of the contract were terms that were also used in the claims of the patent, which is not the case here.

This Order does not depart from the holding in *Gjerlov*. Applying Florida law to the issue of contract interpretation, there is no ambiguity in the License Agreement that would warrant consideration of parol evidence. None of the disputed terms contained in claim 2 of the '1,633 Patent are contained in the License Agreement; therefore, parol evidence relating to the parties' intent in negotiating the terms of the License Agreement would not be helpful in determining patent infringement. Furthermore, although Florida law governs contract interpretation, it does not apply to the determination of patent infringement. The question of whether any of Cordis' products are "covered by any claim of the [Rockey] Patents" is solely a question of federal patent law.

The fraudulent inducement exception to the parol evidence rule is also inapplicable here because this exception allows a fact-finder to consider parol evidence "where the legal existence or binding force of the instrument is in question." *Tinker v. De Maria Porshe Audi, Inc.*, 459 So.2d 487, 491 (Fla. 3d DCA 1984) (citing *Bleemer v. Keenan Motors, Inc.*, 367 So.2d 1036, 1037 (Fla. 3d DCA 1979)). A finding of fraud based on such extrinsic evidence renders an accompanying breach of contract claim moot. *See Lou Bachrodt Chevrolet, Inc. v. Savage*, 570 So.2d 306, 308 (Fla. 4th DCA 1990). AGR did not plead fraudulent inducement. It has never challenged the "legal existence or binding force" of the License Agreement. To the contrary, in its breach of contract claim AGR seeks to enforce the terms of the License Agreement that obligate Cordis to pay royalties.

AGR relies on *Wise v. Quina*, 174 So.2d 590, 596 (Fla. 1st DCA 1965), to argue that "parol evidence is admissible to establish a contemporaneous oral agreement which induced the execution of a written contract, though it may vary, change or reform the instrument." (quoting *Mallard*, 121 Fla. at 664). *Wise* is inapposite. In *Wise*, the plaintiffs wished to enforce an oral representation made by the defendants at the time they purchased a real estate subdivision, but that oral representation did not contradict any provision of the purchase agreement. It is also unclear from *Wise* whether the sale agreement contained a merger clause, as does the License Agreement in this case.

Moreover, as the party wishing to invoke the fraudulent inducement exception, AGR "carries a heavy burden of proof." *Ungerleider*, 214 F.3d at 1282. It would need to establish a purported oral agreement "by evidence that is clear, precise, and indubitable." *Johnson Enter. of Jacksonville, Inc. v. FPL Group, Inc.*, 162 F.3d 1290,13 10 (11th Cir. 1998) (quoting *Mallard*, 121 Fla. at 678) (other citations omitted). Where "the existence of the [supposed] contemporaneous oral agreement rests solely on a credibility choice between two

witnesses," parol evidence, as a matter of law, is **not** "clear, precise, and indubitable." *Id.* (citing *Chase Manhattan Bank v. Rood* 698 F.2d 435, 438 n. 4 (11th Cir. 1983); *Mallard*, 121 Fla. at 678)). Such is the case here. AGR's entire proof of a contemporaneous oral agreement rests on the contradicted testimony of AGR's principal, Gina Rockey Collias. The existence of any supposed extra-contractual "agreement" between the parties is disputed, to say the least, and therefore inadmissible under the inducement exception. *See Johnson*, 162 F.3d at 1310.

Cordis' obligations to pay royalties will be determined based on the language of the License Agreement and proper construction of the Rockey Patents under federal patent law. Parol evidence of any other agreement or understanding between the parties is not be relevant to contract interpretation or claim construction,[9] and is therefore excluded.

2. **Cordis' Motion *in Limine* to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on Products that Practice the Rockey Patents "In Whole Or In Part"**

In opposing Cordis' Motion, AGR argues that the License Agreement "expressly provides that Cordis is liable to AGR for the sale of any stents that incorporate '**in whole or in part**' any of the improvements set forth in the Rockey Patents." (AGR's Response, at p. 5)(emphasis added). Similarly, in opposing Cordis' Motion for Summary Judgment, AGR argues that Cordis is obligated to pay royalties on the sale of any product "that utilized '**in whole or in part**', the inventions **disclosed or claimed** in the Rockey Patents." AGR Response to Cordis' Motion for Summary Judgment, at 1-2 (underlining in original; bold emphasis added). Cordis seeks to

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[9] As discussed *infra* in the section of the Order addressing claim construction and application under federal patent law, claim construction is a matter of law that is "exclusively within the province of the court." *See, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

preclude AGR from offering this reading of the License Agreement in its arguments to the jury.

Cordis' Motion is well taken because, as already noted, paragraph 2.1 of the License Agreement, containing the "in whole or in part" language, does not relate to Cordis' obligation to pay royalties. Moreover, under applicable federal patent law, there cannot be a finding infringement if **any** claim limitation is **literally or equivalently** absent in the accused device. *See, e.g., Techsearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002) ("To establish literal infringement [and infringement under the doctrine of equivalents], **all of** the elements of the claim, as correctly construed, must be [literally or equivalently] present in the accused system") (emphasis added); *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995) ("every limitation set forth in a claim must be found in an accused product"). Accordingly, AGR is precluded from arguing to the jury, or presenting any evidence, regarding Cordis' supposed obligation to pay royalties on products that practice the Rockey Patents "in whole or in part."

3. Cordis' Motion *in Limine* to Exclude or Limit the Testimony of AGR's Patent Law Expert

AGR has identified patent attorney, William H. Murray, Esq. ("Murray"), as one of its expert witnesses. Murray is not a scientist, engineer or physician, and therefore, is not skilled in that relevant art. Murray is a registered patent attorney with 29 years of experience. In this case, Murray bases his opinions on the opinions of Dr. Leonard, including Dr. Leonard's opinions on whether the '010 Application disclosed every limitation of claim 2 of the '1,653 Patent.

Cordis seeks to exclude Murray's testimony, arguing that it will add nothing new. Cordis concedes that patent law experts may testify as to the general procedures involved in the patent application process, but, because they are not themselves experts in the relevant art, they may not testify on

whether the '010 Application discloses every limitation of claim 2 of the '1,653 Patent. Cordis further argues that Murray may not render testify as to the legal requirements for the '1,653 Patent claims to enjoy the benefit of the earlier filing date of the '010 Application, because it is the function of the Court, and not patent law experts, to instruct the jury on applicable law.

AGR maintains that Murray's testimony will be presented to assist the jury in connection with their determination regarding the effective filing date of the Rockey Patents, which, as previously mentioned, is relevant to Cordis' invalidity defense:

> The purpose of Mr. Murray's testimony is to explain to the jury that, based upon his review of the patent's file history, as well as his reliance upon a person skilled in the art, that the Rockey Patents are entitled to an effective filing date of June 1978. Mr. Murray will testify regarding the effect of the patent application process which resulted in the '1,653 Patent. The testimony is relevant to the jury's determination as to whether the work of Palmaz and others after June 1977 constitutes prior art.
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> Mr. Murray will testify that ... there would have been no reason for Dr. Rockey to have filed a continuation-in-part on February 19, 1985.
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> * * *
>
> Put another way, Mr. Murray will testify that based upon his reliance upon the expert, nothing in those applications constitutes new matter sufficient to warrant the filing of a continuation-in-part application [in either 1980 or 1985].

(Response, p. 4.). Furthermore, in his expert report, Murray states that he expects to testify about (1) the issue of PTO

procedures, and in particular whether or not the invention disclosed in claim 2 of '1,653 Patent is entitled to the benefit of the June 2, 1978 filing date of '010 Application in accordance with 35 U.S.C. § 120; (2) in general, the requirements for entitlement to the benefit of an earlier-filed patent application; and (3) the conclusions reached in the expert reports of Drs. Puma and Laird that claim 2 of the '1,653 Patent is not entitled to the benefit of the 1980 filing date of the '989 Application or the 1978 filing date of the '010 Application.

It does appear that AGR intends to offer Murray exclusively as an expert in patent law. The information he expects to provide could be helpful to a jury to clarify the language of the claims as interpreted by the scientific experts. In *Lemelson v. General Mills, Inc.*, 1987 WL 26134, * 1 (N.D. Ill. 1987), for example, the Court denied a motion *in Limine* to exclude the testimony of plaintiff's patent attorney expert on the issues of validity of a claim of the patent at issue and any infringement by defendant of that claim, where his proffered testimony was based both on his expertise in the field of patent law and the technical foundation established at trial by experts in the relevant art. The Court noted that the attorney's "opinions on these issues will merely 'take the further step of suggesting the inference which should be drawn from applying the specialized knowledge [in patent law] to the facts [of toy design art].'" *Id.* (citing Fed.R.Evid. 702, Notes of Advisory Committee on Proposed Rules). In *Lemelson*, the attorney's testimony was offered to show "the relationship of the technical information to the issuance of a valid patent and to determining infringement of such a patent." *Id.* The Court found the testimony admissible under Rule 702 of the Federal Rules of Evidence[10] because "the untrained layman is not

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[10] Rule 702 of the Federal Rules of Evidence addresses testimony by experts and provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to

qualified to assess this relationship intelligently and to the best possible degree without the aid of expert testimony." *Id.* The Court also found that the attorney's testimony would not duplicate the other experts' testimony because, while the other expert testimony would pertain to technical aspects, the attorney's testimony would pertain primarily "to the complex law of patents, including the purpose of patents, patent office procedures and patent prosecution." *Id.* at *2. Here, too, Murray's testimony, preceded by the testimony of the scientific experts on stent technology, may assist the jury in understanding the evidence and determining the facts in issue.

Murray's testimony, if offered, "shall not include any exposition or opinion as to the legal issues in this case or patent law generally." *Ely v. Manbeck*, 17 U.S.P.Q.2d 1252, 1254 (D. D.C. 1990). Murray may explain his own understandings of the law and apply it to opinions of the scientific experts on the issues of fact, without giving expert opinions as to what the law is. *See Reiffin v. Microsoft Corp.*, 270 F. Supp.2d 1132, 1145 (N.D. Cal. 2003) ("Expert testimony of a patent attorney may be admitted, even if the attorney does not have specific expertise regarding the technical field involved in the litigation before the court, because the attorney's familiarity (or lack of familiarity) with that technical field bears on the weight to be accorded the evidence, not the threshold question of admissibility") (citations omitted); *Donnelly Corp. v. Gentex Corp.*, 918 F. Supp. 1126, 1137 (W.D. Mich. 1996) (denying motion *in Limine* to preclude testimony by patent law expert, finding that "experts must walk a fine line: they must give their expert opinions on ultimate issues of fact, while

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determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

explaining their own understandings of the law, but without purporting to give expert opinions as to what the law is"). The Court will provide any "necessary and appropriate instructions to the jury regarding the weight to be accorded to the testimony" after hearing Murray's testimony in light of the testimony of the other experts in the technical field. *Lemelson*, 1987 WL 26134, *2.

Furthermore, Murray may not offer opinions regarding claim construction, infringement, or any other issues of law. He may explain his understanding of the general requirements for entitlement to the benefit of an earlier-filed patent application under 35 U.S.C. § 120, including the meaning of an "effective filing date" and "new matter." He may offer opinions on the relevant background information regarding the patent application process. *See Buckley v. Airshield Corp.*, 116 F.Supp.2d 658, 662 (D. Md. 2000) (allowing patent attorney to testify to the procedures for prosecuting a patent, but precluding any rendering of legal opinions on claim construction and infringement). To the extent that AGR intends to elicit testimony from Murray concerning the general procedures involved in the patent application process, such testimony may be helpful to the jury, and is therefore admissible. *See, e.g., Bausch & Lomb, Inc. v. Alcon Laboratories, Inc.*, 79 F.Supp.2d 252, 255 (W.D. N.Y. 2000); *Revlon Consumer Prod Corp. v. L'Oreal SA.*, 1997 WL 158281, *3 (D. Del. 1997) (defendants' expert would be allowed to "testify only as to matters of PTO practice and procedure"); *Cameco Indus., Inc. v. Louisiana Cane Mfg., Inc.*, 1995 WL 468234, * 4 (E.D. La. 1995) (permitting expert to testify "about the patent application process, the operations and functions of the patent and trademark office, and the materiality of the relevant art"). Murray is also permitted to offer opinions regarding whether or not the invention disclosed in claim 2 of the '1,653 Patent is entitled to the benefit of the June 2, 1978 filing date of the '010 Application in accordance with 35 U.S.C. § 120, and he may respond to the conclusions reached in the expert reports

of Drs. Puma and Laird that claim 2 of the '1,653 Patent is not entitled to the benefit of the 1980 filing date of the '989 Application or the 1978 filing date of the '010 Application. *See Bausch & Lomb*, 79 F. Supp.2d at 257 (permitting patent law expert to testify regarding the factual bases for his opinion on the effective filing date of a patent based on the testimony of scientific experts). Such testimony is relevant to the determination of whether the work of Dr. Palmaz constitutes prior art.

4. Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents

Cordis seeks to exclude the expert opinions of AGR's experts, Widas, Dr. Pope, and Dr. Leonard, on infringement under the doctrine of equivalents because these experts did not offer any opinions on the doctrine of equivalents in their expert reports or in their depositions. Cordis further argues that the declarations by AGR's experts that were submitted in response to Cordis' Motion for Summary Judgment are insufficient because they merely parrot the legal standard set forth in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950), without providing the detailed factual analysis that is necessary to show infringement under the doctrine.

With regard to Cordis' first argument, AGR's experts will be permitted to opine on the doctrine of equivalents at trial despite the untimely disclosure of the opinions. However, **at Cordis' request, AGR shall make its experts available for additional depositions by Cordis to probe their opinions relating to the doctrine of equivalents prior to trial.** Cordis' second argument for exclusion is rejected for the reasons provided *infra* on the Motion for Summary Judgment.

5. Cordis' Motion *in Limine* to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert*

Mr. Widas and Dr. Leonard have testified that after expansion of the balloon, Cordis' stents increase in rigidity to an infinitesimally small extent, which admittedly, they have not tried to measure. Cordis seeks to exclude this testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

There are conflicting expert testimony, literature, and other evidence, that bear on whether the opinions expressed by Mr. Widas and Dr. Leonard are true. On this record, the undersigned cannot determine that the scientific opinions expressed by Mr. Widas and Dr. Leonard are completely lacking in scientific reliability, as is required for expert testimony to be excluded under *Daubert*. It will the function of the jury to weigh the conflicting evidence and make credibility determinations, with proper instructions from the Court on the applicable law. Accordingly, the Motion *in Limine* to exclude Certain Testimony by Mr. Widas and Dr. Leonard is denied.

6. Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard

Cordis' Motion to Strike the Supplemental Report of Dr. Leonard is premised on the same grounds as Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents. For the reasons previously outlined, this Motion is also denied. The Supplemental Expert Report of Edward F. Leonard is accepted as filed.[11]

C. CORDIS' MOTION FOR SUMMARY JUDGMENT, AND MOTION FOR CONSTRUCTION OF TERMS IN THE CLAIMS OF THE ROCKEY '1,653 PATENT

1. Legal Standard on Summary Judgment

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[11] The Supplemental Expert Report of Dr. Leonard was filed as Exhibit 4 to Cordis' Motion to Strike, and as Exhibit A to AGR's Memorandum in Opposition to Cordis' Motion to Strike.

Under Rule 56(c), Fed. R. Civ. P., a motion for summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The Supreme Court explained the movant's burden in *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986) as follows:

> In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.

Id. at 322. The Court further stated that "Rule 56(c) therefore requires a non-moving party to go beyond the pleadings and by [its] own affidavits or by the 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324.

By its very terms, this standard provides that the mere existence of "*some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there will be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). An issue is "material" if it is a legal element of the claim under the applicable substantive law which might affect the outcome of the case. *Anderson*, 477 U.S. at 248; *Allen v. Tyson Foods*, 121 F.3d 642, 646 (11th Cir. 1997). An issue is "genuine" if the record taken as a whole could lead a rational trier of fact to find for the non-moving party. *Allen*, 121 F.3d at 646. On a motion for summary judgment, the Court must view all the evidence and all factual inferences drawn therefrom in the light most favorable to the non-

moving party, and determine whether that evidence could reasonably sustain a jury verdict. *Celotex*, 477 U.S. at 322-23; *Allen*, 121 F.3d at 646.

While the burden on the movant is great, the non-moving party has a duty to present affirmative evidence in order to defeat a properly supported motion for summary judgment. *Anderson*, 477 U.S. at 252. A mere "scintilla" of evidence in favor of the non-moving party, or evidence that is "merely colorable" or "not significantly probative," is not enough. *Id.*; *see also Mayfield v. Patterson Pump Co.*, 101 F.3d 1371, 1376 (11th Cir. 1996) (conclusory allegations and conjecture cannot be the basis for denying summary judgment). Moreover, otherwise admissible evidence may be submitted in inadmissible form at the summary judgment stage. *See McMillian v. Johnson*, 88 F.3d 1573, 1584-85 (11th Cir. 1996); *Gaston v. Home Depot USA, Inc.*, 129 F. Supp.2d 1355, 1361 (S.D. Fla. 2001)

2. Failure to Pay Royalties (Count I)

a. *Patent Infringement Analysis*

There are two ways for a plaintiff to show patent infringement: literal infringement or infringement by equivalence, referred to as infringement under "doctrine of equivalents." A literal infringement analysis involves two steps: (1) proper interpretation of the asserted patent claim(s) (*i.e.*, "claim construction") to determine their scope and meaning; and (2) comparison of the properly interpreted claim(s) and the defendant's product (*i.e.*, claim application) in order to determine whether the claims can be read onto the accused product. *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1207 (Fed. Cir. 2001); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580-81 (Fed. Cir. 1996). The first step, claim construction, is a question of law, while the second step, claim application (*i.e.*, the determination of "infringement") is a question of fact. *Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc.*, 261 F.3d 1329, 1336 (Fed. Cir.

2001). However, literal infringement based on claim construction is amenable to resolution by summary judgment where the parties do not dispute the relevant facts regarding the accused product, but merely disagree over claim interpretation. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996); *Johnson v. IVAC Corp.*, 885 F.2d 1574, 1579-80 (Fed. Cir. 1989); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997). The patentee bears the burden of proving infringement by a preponderance of the evidence. *Advanced Cardiovascular Systems*, 261 F.3d at 1336.

In construing the patent claims, the trial court must discern the ordinary and customary meanings attributed to the words used. Standard dictionaries of the English language may help identify the ordinary meaning of a claim term. *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002); *Inverness Medical Switzerland v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1369 (Fed. Cir. 2002); *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334-35 (Fed. Cir. 2000). Once the court has determined the ordinary and customary meaning of the terms, there is a heavy presumption that those definitions are the proper meanings. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art."). Thus, patent infringement analysis begins and must remain focused upon the words of the patent claims themselves to determine the ordinary and customary meanings of those terms. *Id.*

After the court has determined the ordinary and customary meanings of the terms at issue, it may then look to the rest of the intrinsic evidence, including the patent specification and file history. "[I]f an invention is disclosed in the written description in only one exemplary form or in only one embodiment, the risk of starting with the intrinsic record is that the

single form or embodiment so disclosed will be read to require that the claim terms be limited to that single form or embodiment." *Texas Digital Systems*, 308 F.3d at 1205 ("'That a specification describes only one embodiment does not require that each claim be limited to that one embodiment.' . . . Indeed, one can easily be misled to believe that this is precisely what our precedent requires when it informs that disputed claim terms should be construed in light of the intrinsic record.") (citing *Teleflex, Inc.*, 299 F.3d at 1328); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995); *SRI Int'l, Inc. v. Matsuchita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). Therefore, "[a]lthough the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish or vary' the limitations in the claims." *Markman*, 52 F.3d at 979.

An analysis of the intrinsic record is particularly important because words often have multiple dictionary meanings. The intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is 'most consistent with the use of the words by the inventor." *Texas Digital Systems*, 308 F.3d at 1203-04 ("'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'") (citing *Dow Chemical Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372-73 (Fed. Cir. 2001)); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*,, 334 F.3d 1294, 1300 (Fed. Cir. 2003) ("[T]he general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context. . . . 'Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings. "') (citation omitted). "[T]he claims must be read in view of the specification , . . . but limitations from the specification are not to be read into the

claims." *Teleflex*, 299 F.3d at 1326. The file history must also be considered. *Id.* at 1324-25. "Among the intrinsic evidence, 'the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1325 (quoting *Vitronics*, 90 F.3d at 1582); *Markman*, 52 F.3d at 979 (Dictionary definitions are a useful first step, but "[c]laims must be read in view of the specification , of which they are a part."); *Bell Atlantic Network Serv. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) (The intrinsic evidence, *i.e.*, the surrounding claim language, the patent specification and the file history - provide "'the most significant source of the legally operative meaning of disputed claim language.'") (quoting *Vitronics*, 90 F.3d at 1582). Claims should be construed to encompass all definitions that are consistent with the use of the word in the intrinsic record, except those that have been disclaimed. *Brookhill-Wilk*, 334 F.3d at 1299 ("If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim may be construed to encompass all consistent meanings."); *see also Texas Digital*, 308 F.3d at 1203 (same).

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583 (citations omitted). There are only two situations where a sufficient reason exists to require the construction of a claim term to mean something other than its ordinary and accustomed meaning. The first occurs where the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term. *Vitronics*, 90 F.3d at 1582 ("Although words in a claim are generally to be given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the terms is clearly stated in the patent specification or file history.") (citing *Hoechst*

Celanese Corp. v. BP Chemicals, Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996)). The second arises where the term or terms chosen by the patentee so deprive the claim of clarity that there is "'no means by which the scope of the claim maybe ascertained from the language used.'" *Bell Atlantic*, 262 F.3d at 1268 (citing *Johnson v. Worldwide Assoc. Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)). "Where a patentee has clearly defined a claim term, that definition is usually dispositive." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1360 (Fed. Cir. 2002).

A court may also consider extrinsic evidence, such as expert testimony, as to how those skilled in the art would interpret the claims. However, a court should not rely on expert testimony or other extrinsic evidence if the intrinsic evidence establishes the proper construction of the claims. "I[f] an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence." *Brookhill*, 334 F.3d at 1304 (quoting Vitronics, 90 F.3d at 1582). The Federal Circuit has consistently emphasized that "extrinsic evidence," *i.e.*, anything outside of the intrinsic evidence - may not be used in claim construction to vary the meaning of claim terms as reflected in the intrinsic record. *Vitronics*, 90 F.3d at 1583. In particular, "[e]xpert testimony . . . may not [be used to] ... diverge from the description of the invention as contained in the patent documents." *Aqua-Aerobic Sys., Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1245 (Fed. Cir. 2000). Although the court may rely on the evidence from experts "to educate itself about the patent and the relevant technology, the claims and the written description remain the primary and more authoritative sources of claim construction." *Mantech Envtl. Cor. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998).

After the court has construed the claims of the patent, the properly construed claims must be compared to the accused device or method to determine whether the latter has "all of the claim limitations." *Techsearch, L.L.C. v. Intel Corp.*, 286

F.3d 1360, 1371 (Fed. Cir. 2002). To establish literal infringement, AGR must show that "every limitation set forth in a claim [is] found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). If any limitation is absent, there cannot be a finding of infringement.

If there is no literal infringement, a device or method may nonetheless infringe a patent under the doctrine of equivalents. *Sage Products, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997) ("A device that does not literally infringe a claim may nonetheless infringe under the doctrine of equivalents if every element in the claim is literally or equivalently present in the accused device."). One way that a plaintiff may show infringement under the doctrine of equivalents is by establishing that the offending device or method functions in substantially the same way to achieve substantially the same result as the device or method covered by the patent. *Graver Tank*, 339 U.S. at 608. Another way is by showing that the claim limitation or element is "equivalently present" in the accused device because there are only "insubstantial differences" between the missing claim limitation or element and corresponding aspects of the accused device. *Zodiac Pool Care, Inc. v. Hoffinger Industries, Inc.*, 206 F.3d 1408, 1415 (Fed. Cir. 2000). Equivalence must be considered on a limitation-by-limitation basis; in other words, it must be determined whether **each** of the claim limitations are "equivalently present" in the accused product.

Although the doctrine of equivalents usually presents an issue of fact for the jury, "where the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

b. Claim Construction and Application

The following is an analysis of the language of claim 2 of the Rockey '1,653 Patent that begins with the ordinary dictionary meanings of the words provided by the parties and determines which of the ordinary meanings are consistent with the intrinsic record, and if more than one is consistent, then which meaning is most consistent with the surrounding words, the Patent specification and the file history. No extrinsic evidence has been considered in arriving at the proper construction of the claim terms. The Rockey invention disclosed by the properly construed claims is then compared to the Cordis stents.

i. The Proper Construction of the Terms of Claim 2 of the '1,653 Patent

"Introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated"

This claim limitation requires that a flexible tube of metal, rubber or plastic (the catheter) be inserted into a vessel, at a point remote from the area of the body to be treated (*i.e.*, the part where the sleeve ultimately will be placed and will remain), with a balloon and a sleeve that are both folded together compactly, and in such a way that the sleeve, which is capable of isolating material flowing into the vessel from direct contact with the interior surface of the vessel, surrounds the balloon and both the balloon and sleeve are positioned at or near an extremity of the catheter.

(a) Undisputed Terms

The parties agree that the following ordinary meanings of terms are consistent with the intrinsic record, and the Court adopts these meanings as consistent with the intrinsic record:

1. "Introducing" means *inserting or injecting.* (American Heritage Dictionary of the English Language (1980)) (hereinafter "American Heritage Dict.").

2. "Catheter" means a "*flexible tube of metal, rubber, or plastic inserted into a body channel, such as a vein, to distend or maintain an opening to an internal cavity.*" (American Heritage Dict.).

3. "Inflatable" means *capable of becoming inflated; swelling; expanding.* (American Heritage Dict.).

4. "Balloon" means "*[a]rt elastomeric membrane completely enclosing a volume which expands when the volume of the fluid occupying that space or volume is increased, i.e. a rubber sack which may be inflated.*" (The Grosset Webster Dictionary (1966)).

5. "Vessel" means "*a tube or canal (as an artery) in which a body fluid is contained, conveyed or circulated.*" (Webster's Ninth New Collegiate Dictionary (1983)) (hereinafter "Webster's Ninth").

6. "Point" means "*a position, place or locality; spot.*" (American Heritage Dict.).

7. "Remote" means "*located far away; relatively distant in space.*" (American Heritage Dict.).

8. "Area" means "*any particular extent of space, surface, or region.*" (The Random House College Dictionary, Revised Ed. (1988)) (hereinafter "Random House").

9. "Treated" means *cared for or dealt with medically or surgically.* (Webster's Ninth).

(b) "Collapsed"

Cordis contends that a "collapsed" balloon or sleeve is a balloon or sleeve that has been reduced in bulk by being folded (*i.e.*, doubled over) into a more compact space. Cordis relies on the definition of "collapsed" as "[t]o fold compactly," provided in the American Heritage Dictionary of the English Language (1980). Cordis further relies on the definitions of fold as "to lay one part over another part of: double upon itself" (Webster's Third New International Dictionary of the English Language Unabridged (1986)) (hereinafter "Web-

ster's Third"), or "to reduce the length or bulk of by doubling over." (Webster's New Collegiate Dictionary (1981)). In contrast, AGR proposes the following definitions of "collapsed": (1) "[t]o fold or come together compactly;" (Webster's New Twentieth Century Dictionary (1977)) (hereinafter "Webster's Twentieth"); (2) "to fall together or in" (Webster's Twentieth); (3) "[t]o fold compactly" (American Heritage Dict.); (4) "[t]o be made so that parts can be folded, placed, etc., together" (Random House); and (5) "to fall or shrink together abruptly and completely; fall into a jumbled or flattened mass through the force of external pressure" (Webster's Ninth).

The Court has reviewed all of the foregoing dictionary definitions of the word "collapsed" in the context of the other words used in the '1,653 Patent, as well as the corresponding specification and file history. The surrounding text, specification and file history support the following construction of the word "collapsed," which is the one the Court adopts: *folded together compactly so that one part is laid over another part.* The following statements included in the Patent claim and specification support such a construction of the word "collapsed" that is limited to materials that may be "folded" or "doubled over" to fit into a more compact space:

> 1. "[T]he sleeve is **sufficiently flexible** to be collapsed into a unit of relatively low bulk for ease of passage through the posterior pharynx and esophagus." (Summary of the Invention, 2:19-23) (emphasis added).
>
> 2. "Fig[ure] 5 of a view of the sleeve unit in a **compacted** condition .." (Brief Description of the Drawings, 3:3-4) (emphasis added). Figure 5 is a drawing showing the disclosed sleeve with its parts folded compactly with some of it parts laying over or on other parts and contained in what is referred to as a "dilator shell or cup." Figure 6 shows the parts of the sleeve unfolding, or coming apart, after the dilator shell or cup is removed.

Dr. Rockey describes the process in Fig. 6 as follows: "Lower sections of the filaments ... associated with the sheath [sleeve] 11 . . . **unfold** themselves along with the sheath [sleeve]." (Description of the Preferred Embodiment, 4:24-27) (emphasis added).

3. "The sheath 11 [sleeve] in the illustrated example if [sic] a **flexible** membrane..." (Description of the Preferred Embodiment, 3:24-25) (emphasis added).

4. Referring to Figs. 5, 6 and 7, Dr. Rockey instructed that "[t]o facilitate introduction of the sleeve unit 10 into the stomach 32, the sleeve unit is **folded on itself accordion fashion** to reduce its length and diameter." (Description of the Preferred Embodiment, 4:9-12) (emphasis added).

5. "In its **folded or compacted** state, the sleeve unit 10. ." (Description of the Preferred Embodiment, 4:12-13) (emphasis added). Here, Dr. Rockey uses the words "folded" and "compacted" as synonyms.

6. In the preferred embodiment in Fig. 9, Dr. Rockey indicates that "[t]he collapsed state can be maintained by **wrapping the sleeve 51 on itself**," (Description of the Preferred Embodiment, 4:11-13; 6:43-44) (emphasis added), which is followed by insertion of the pressure of a liquid that inflates the balloon. "The pressure of this inflating fluid is sufficient to break the light heat bonds holding the **folds of the sleeve** together and to expand the sleeve .." (Description of the Preferred Embodiment, 6:48:51) (emphasis added).

7. "The balloon ... is formed of any suitable plastic or rubber material which may be **folded** and/or expanded." (Description of the Preferred Embodiment, 6:7-9) (emphasis added).

Thus, Dr. Rockey used the word "folded" to describe multiple drawings and embodiments disclosed in the '1,653 Patent, not just one preferred embodiment. The '1,653 Patent file

history also uses the words "collapsed" and "folded" interchangeably. The instances where Dr. Rockey uses the words interchangeably are numerous and will not recited here, but one example may be found in Dr. Rockey's '010 Application. The '010 Application is similar to the '1,653 Patent in its description of the preferred embodiment of the sleeve as being "sufficiently flexible to be collapsed into a unit of relatively low bulk" for ease of delivery through narrow body passageways. As advanced by Cordis, the original claims of that application call for a sleeve that is "sufficiently flexible to be folded on itself to thereby reduce its bulk ... to facilitate initial placement of the sleeve into the body vessel." Although neither the word "fold" nor the phrase "folded on itself" was actually included in the language of Dr. Rockey's Patent claims, this language chosen by Dr. Rockey and included in his first application and throughout his three related patent file histories constitutes further evidence that when Dr. Rockey wrote "collapsed," he meant "folded," *i.e.*, "doubled over." Accordingly, the requirement that the balloon and the sleeve must be "folded together compactly" may properly be read into claim 2 of the '1,653 Patent.

(c) "Sleeve"

Cordis argues that the term "sleeve" should be construed to cover an impervious liner, *i.e.*, one without holes or openings, suitable for isolating the wall of a body vessel from materials that otherwise could come into contact with it. Cordis cites to *Alloc, Inc. v. US Int'l Trade Comm'n*, 2003 U.S. App. LEXIS 18744 (Fed. Cir.). The patent claims in *Alloc* did not mention a "play" or space between the components of the claimed locking joint, and "play" was not part of the dictionary definition of any claim term. Nonetheless, the Federal Circuit construed the claims as requiring "play" because the specification described "the invention" - not merely a preferred embodiment, but rather, the invention itself - as a locking joint with "play." *Id.* at 15. Moreover, the specification did "not show or suggest any systems without play." *Id* at 18.

Under these circumstances, the Federal Circuit construed the claims as requiring "play," even though "play" was not mentioned in the claims. As the Federal Circuit explained (*id.* at 19-20):

> [The] Court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. . . . [W]here the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.

See also SciMed Life Ins., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 58 2001) (discussed with approval in *Alloc*).

Throughout the '1,653 Patent specification , Dr. Rockey's invention - not merely a preferred embodiment, but the invention itself - is described as a sleeve that isolates body vessel from material normally flowing into it. This theme starts on the first page of the Patent, when the Patent Abstract summarizes the '1,653 invention as "comprising a sleeve unit . . . **to isolate material flowing into the vessel from direct contact with the interior surface of the vessel.**" (emphasis added). The section of the '1,653 specification entitled "Summary of the Invention" goes on to describe Dr. Rockey's "invention" (again, not merely a preferred embodiment, but the invention itself) in the same fashion: "The invention provides a method and means for **isolating the internal walls of hollow viscera or other body vessels from contact with materials, both fluids and solids, occurring naturally, ingested or otherwise introduced into a body vessel.**" (Summary of the Invention, 1:54-58) (emphasis added). The "Summary of the Invention" further states that the "tissue isolating function of the disclosed sleeve," in addition to control of the mechanism

of digestion, has numerous other applications . . . ." (Summary of the Invention, 2:33-36). These include using the "sleeve ... to chemically and/or physically protect tissue which has been ulcerated, herniated, fissured, or the like from natural body fluids," *id.* at 2:37-40, which can be done by "isolating the effect of normal blood pressure from the vessel by containing it within the sleeve." *Id.* at 2:42-44. The Summary of the Invention also provides (*id.* at 1:58-64): "**Isolation of a body vessel according to the invention**, is achieved by positioning and anchoring a sleeve, impervious to materials sought to be isolated within the vessel ...." (emphasis added).

Every embodiment described in the Patent is capable of serving this "isolating" function. For example, the "sleeve unit" of the embodiment in Fig. 1, for use in the digestive system, is described as being "implanted in a body vessel in order **to isolate** the walls of such vessel from fluids normally flowing into it." (Description of the Preferred Embodiment, 4:1-3) (emphasis added). Figure 4 illustrates "a manner of use of the sleeve unit 10 **to isolate** the internal surface area or lumen, designated 31, of a human stomach 32 and its secretions from food substances passing through it." (*Id.* at 4:3-7) (emphasis added). The specification further states as to Figure 4 that the sleeve reduces the digestive efficiency of the stomach "by **isolating** the walls 31 of the stomach 32 from ingested food passing through it . . . ." (*Id.* at 5:6-8).

The other embodiments of the '1,653 Patent are described in similar terms. For example, an embodiment of the sleeve shown in Figure 8 and intended for use in the aorta, is described as having "a construction essentially the same as the earlier described in sleeve 10." (Ex. 3 at 5:31-32). According to the specification , this permits "blood flowing through the sleeve [to be] effectively **isolated** from the vessel." (*Id.* at 5:55-56) (emphasis added). The remaining embodiment, shown in Figure 9, is described as suitable for use in a body vessel requiring "**isolation** or like treatment." (*Id.* at 5:59-61)

(emphasis added). The sleeve of this third embodiment has inner and outer walls that are capable of isolating the vessel wall because they are "imperforate" (*id.* at 6:10-11), and these imperforate walls are "joined in a fluidtight manner ... ." (*Id.* at 6:12).

Each of the figures of the '1,653 Patent, and the only sleeves described in the Patent, show a sleeve that can isolate the vessel wall from materials with which it would otherwise come into contact. Indeed, the Patent does not disclose or suggest any embodiment of the sleeve that could not perform this "isolating" function. The term "sleeve" means the type of sleeve that Dr. Rockey described as his invention, *i.e.*, a part that can perform this tissue-isolating function.

AGR's experts take the position that the term "sleeve" should be defined as "a tubular part (such as a hollow axle or bushing) designed to fit over another part." (Webster's Ninth). This definition, however, does not comport with Dr. Rockey's description of his "medical sleeve" in the ' 1,653 Patent. The definition of "sleeve" that the inventor adopted, implicitly or explicitly, in his specification is the one that should be given effect. As the Federal Circuit has held:

> [A] claim term may be clearly redefined [in the specification] without an explicit statement of redefinition. Indeed, we have specifically held that the written description of the preferred embodiments 'can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.'

Bell Atlantic, 262 F.3d at 1268 (quoting *SciMed Life Sys.*, 242 F.3d at 1344). "In other words, the specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" *Id.* (quoting *Vitronics*, 90 F.3d at 1584 n.6). *See also Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1367

(Fed. Cir. 2003) ("The applicant may also act as his own lexicographer and use the specification to implicitly or explicitly supply new meanings for terms.") (emphasis added); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003) (same); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1374-75 (Fed. Cir. 2003) (basing construction of the term "automation code" on the use of that term in the specification where dictionary definitions did not provide meaningful guidance on the usage of that term in the patent).

In *Bell Atlantic*, 262 F.3d 1258, for example, the Federal Circuit held that the patentee implicitly defined the term "mode" so that it had a narrower definition than the ordinary dictionary definition. Although the word "mode" had an ordinary meaning, the Federal Circuit did not end its analysis there. Instead, it went on to examine the specification :

> It may be true that the ordinary meaning of the word 'mode' supports a broader meaning than the construction ascertained by the district court. However, we must look at the intrinsic evidence to determine whether the patentee has given the term an unconventional meaning.

Id. at 1269. In construing the claims, the Federal Circuit relied extensively on the patentee's repeated references to the purpose of the invention, including those in the summary of the invention. *Id.* at 1269-73. Based on the implicit definitions in the specification , the court construed the term "mode" to be limited to the embodiments actually disclosed in the specification and not to the broader ordinary meaning (*id.* at 1273):

> We acknowledge that it is generally impermissible to limit claim terms by a preferred embodiment or inferences drawn from the description of a preferred embodiment. However, that is not the case here. We note that '[t]he usage 'preferred' does not of itself broaden the claims beyond their support in the specification .' Moreover, unlike Johnson v. Worldwide, this case does not involve the '[v]aried use of a disputed term.' Instead,

> the patentees defined the term 'mode' by implication, through the term's consistent use throughout the '786 patent specification . Given this definition, the three modes described in the Detailed Description of the Preferred Embodiments describe the three possible modes of the invention, and the claims are not entitled to any broader scope.

The '1,653 specification as a whole is replete with descriptions of Dr. Rockey's "sleeve" as capable of isolating the vessel wall from contact with materials. That definition is one that Dr. Rockey implicitly or explicitly adopted, and it governs. *See Bingo Brain, Inc. v. Cal. Concepts, Inc.*, 2002 WL 99272, at *3-5 (N.D. Ill. 2002), *aff'd* 53 Fed. Appx. 75 (Fed. Cir. 2002) (court relies on implicit definition in specification to limit claim term "bingo cards" to physical bingo cards and not to include virtual bingo cards); *Wang Lab, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999) (claim term interpreted more narrowly than its ordinary meaning and limited in accordance with the specification , which described a particular feature as part of the invention); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295 (Fed. Cir. 1999) (claim term interpreted in accordance with specification and drawings, which showed a particular structure, did not illustrate or describe any other structure, and described the advantages of the featured structure as important to the invention); *Chiron Corp. v. Genentech, Inc.*, 266 F.Supp.2d 1172, 1198 (E.D. Cal. 2002) (inventor acted as his own lexicographer of "immunoassay" based on the purposes of the patent").

Nevertheless, and contrary to the position adopted by Cordis, Dr. Rockey did not require that the sleeve be completely "impervious." Although he makes several references to the "sleeve" as an "impervious" liner, he does not describe it in such a way in the Abstract section of the Patent specification . As previously mentioned, he does specify in the Abstract that the sleeve unit must isolate material flowing into the vessel from direct contact with the interior surface of the

vessel. Although an impervious material would accomplish the "isolating" function, it is conceivable that a device that is not completely impervious could nonetheless isolate some materials from the vessel. Moreover, the term "impervious" is not used to describe all of the preferred embodiments. The critical aspect of Dr. Rockey's invention is the "tissue isolating function," as it is described as the only feasible design in the disclosure. As far as the "shape" of the "sleeve," Dr. Rockey provides that it may be cylindrical, tubular, or "it may take other configurations, such as a frustrum or a sphere truncated adjacent opposite poles, or a tubular elbow of constant and varying diameter." (Description of the Preferred Embodiment, 3:39-44).

AGR relies on the section of the Patent specification that provides that "the sleeve can include a weave or mesh outer layer (not shown) which will lie against and adhere to the wall to the blood vessel." (Description of the Preferred Embodiment, 6:17-21). In this sentence, Dr. Rockey refers to the "outer layer" of the sleeve, which may be made of weave or mesh. Dr. Rockey also writes, however, that "[t]he inner wall 61 may be formed of Teflon so that cells will not readily adhere to this area." (*Id.*). Accordingly, the sleeve's inner layer performs the isolating function in this embodiment.

AGR does not deny that the specification of the '1,653 Patent describes Dr. Rockey's invention as a sleeve that can isolate the wall of a body vessel from material that otherwise would come into contact with it. Nor does it deny that every embodiment in the Patent is capable of performing that isolating function. And AGR cannot point to any different use of the term "sleeve" in the '1,653 Patent. The term "sleeve" accordingly should be given the meaning it has in the specification of Dr. Rockey's Patent.

Because the specification of the '1,653 Patent describes Dr. Rockey's "invention" - not just a preferred embodiment, but the invention itself as a sleeve that can isolate the wall of

a body vessel from material that otherwise would come into contact with it, the Court will adopt the meaning attributed by Dr. Rockey to his invention. Thus, a "sleeve" refers to *a cylinder, tube, frustum or sphere insertable into a body vessel and capable of isolating material normally flowing into the vessel from direct contact with the interior surface of the vessel.*

(d) "Encircling the Balloon on its End"

There appears to be no dispute regarding the meaning of the word "encircling." The following construction agreed to by the parties, which is consistent with the intrinsic evidence, is therefore adopted:

"Encircling" means *forming a circle around, surrounding.*" (Webster's Ninth).

Here agreement ends. Cordis argues that this limitation requires that the sleeve must be positioned at the balloon's "extreme or last part lengthwise," which is one definition of "end" provided in Webster's Ninth New Collegiate Dictionary. AGR argues that the following other definitions of the word "end" also provide a proper construction: (1) "the part **at, toward, or near either of the extremities** of anything; tip" (Webster's Twentieth); (2) "[e]ither extremity of something that has length" (Random House); (3) "[t]he outside or extreme edge or limit of a space, form, or event; a boundary" (Random House); (4) "a part or place **at or adjacent to an extremity**" (Webster's Ninth) (emphasis added); (5) "the part of an area that **lies at the boundary**" (Webster's Ninth).

The parties also dispute whether "on **its** end" refers to the end of the balloon, which is Cordis' construction, or the end of the catheter, AGR's construction. According to AGR, this limitation indicates that the catheter has both a collapsed inflatable balloon and a collapsed sleeve encircling the balloon **on the end of the catheter**. That is, the claim requires that each of those two elements - the collapsed balloon and the

collapsed sleeve - be "on its end," referring to the catheter; otherwise, there would be no information as to where the inflatable balloon is located on the catheter. Thus, AGR argues, that, when properly read, the phrase indicates that this element of the claim includes a catheter that has both a collapsed inflatable balloon and a collapsed sleeve located at the end of the catheter.

Figure 9 from the '1,653 Patent specification shows that the sleeve and the balloon are both located at the extreme or last part lengthwise of the catheter, and not at or near an extremity. This picture of one preferred embodiment is the only intrinsic evidence that supports the meaning of end as "the extreme or last part lengthwise." There is no language in the Patent itself or in the specification or history that limits explicitly or implicitly the meaning of end to "the extreme or last part lengthwise." Therefore, the Court will not construe the term to include such a limitation.

Based on the drawing in Figure 9, the disclosed sleeve encompasses or covers the balloon, but is not on the end of the balloon; that is, the sleeve in the disclosed embodiment is located over the balloon and not at either end of the balloon. Moreover, there is other evidence contained within the specification that renders the "on its end" limitation applicable to the end of the catheter rather than the end of the balloon. In the description of the embodiment depicted in Figure 9, Dr. Rockey wrote "catheter 54 having a dilator annular balloon 50 **at its free end** [the end of the catheter that is not being "manipulated" by the user of the invention as indicated in the next claim limitation: "manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated"] and the sleeve 51 surrounding the balloon is threaded through the vessel 52 from an incision made in the vessel..." (emphasis added). Here, too, he describes a catheter having a balloon and a sleeve on the "free end" of the catheter.

The construction of the term "end" that is most consistent with the surrounding text and the specification is *the part at, toward, or near an extremity lengthwise*. Accordingly, the phrase "encircling the balloon on its end" requires that the sleeve encircle the balloon on a part at, toward or near an extremity of the catheter.

"Manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated"[12]

Cordis argues that based on the ordinary meaning and intrinsic evidence, this claim limitation requires someone to handle the catheter so that the balloon and sleeve move through the vessel until the balloon and sleeve are in the region to be treated. Cordis' construction is based on the definitions offered by AGR and used by AGR's experts in their analysis. In its briefs, AGR has not offered a proposed construction of this phrase. The only dispute between the parties with regard to this claim limitation is that Cordis argues that the Court must choose the meaning for each term that is **most consistent** with the Patent and its history, while AGR maintains that the Court must adopt every proposed meaning because all are consistent. Not only does the law require that the Court choose the most consistent meaning as its claim construction, see supra, but this makes the most sense since offering a jury six or seven definitions or meanings of a term would not provide meaningful guidance.

The following ordinary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

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[12] The Court finds that the inventor attributed the same meaning to a particular term every time it appears in claim 2. Therefore, where a term has been previously construed, such as in this case the terms "catheter," "vessel," "balloon," "sleeve," "area" and "treated," the construction applies as to each claim limitation containing the term.

1. "Manipulating" means "treating or operating with the hands or by mechanized means in a skilled manner." (Webster's Ninth).

2. "Axially" means in the direction of a central line bisecting a body, form or the like. (Random House).

3. "Enter" means "to go or come in." (Webster's Ninth).

Accordingly, this claim limitation requires someone to handle the catheter with his or her hands so that the attached balloon and sleeve move through the vessel until the balloon and sleeve are in the region to be treated.

"Inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel"

Once again, the parties do not dispute that all of the dictionary definitions offered by AGR are consistent with the intrinsic record. The only question is how many meanings should be attributed to the terms, and which meaning for each term is most consistent with the words of the inventor in the Patent specification and file history.

The following ordinary dictionary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

1. "Inflating" means *distending, swelling or puffing out.* (Random House).

2. "Fluid" means *"[a] substance, as a liquid or gas, that is capable of flowing and which changes its shape at a steady rate when acted upon by force."* (Random House).

3. "Pressure" means *"[t]he application of force to something by something else in direct contact with it."* (Webster's Ninth).

4. "Tube" means *"[a] hollow elongated cylinder."* (Webster's Ninth).

5. "Manner" means "*way of doing, being done, or happening.*" (Random House).

6. "Surrounding" means *enclosing on all sides; encompassing; forming an enclosure around; encircling.* (Random House).

7. "Radially" means *"[m]oving in the direction of a radius; going from the center outward or from the circumference inward along a radius."* (Random House).

8. "Expanded" means *opened up; increased in extent, number, volume or scope of; opened out.* (Webster's Ninth).

9. "Towards" means *"[i]n the direction of."* (Random House).

10. "Wall" means *"[a] material layer enclosing space."* (Webster's Ninth).

Accordingly, this claim limitation requires the insertion under force of a fluid substance into the balloon through a tube of the catheter causing the balloon and the sleeve encompassing or enclosing the balloon to increase in extent, size or volume in the direction of a radius and in the direction of a layer of the vessel that is being treated.

"Providing in the sleeve a material which increases in rigidity after expansion of said balloon"

(a) "Providing in the Sleeve a Material"

The meaning of the term "material" is undisputed. Therefore, the following ordinary meaning of "material" is adopted as the one that is most consistent with the intrinsic record: *"[t]he substance or substances of which a thing is made or composed."* (Random House).

The words "providing" and "in" are the terms in dispute. Cordis argues that this limitation requires the act of supplying

in a materially bounded object, *i.e.*, the sleeve, a material that is separate and distinct from the sleeve itself. AGR argues that Cordis seeks to wrongfully limit this phrase by contending that it requires providing in the sleeve an *additional* material that increases in rigidity. AGR's proposed construction is that the claim limitation requires that the sleeve itself, or alternatively, an additional material added to the sleeve, be made of a material that increases in rigidity.

Cordis proposes that the meaning of "provide" is "to supply or make available; to make something available to" (Webster's Ninth), and the word "in" "indicate[s] location in space or in some materially bounded object." (Webster's Third). Thus, according to Cordis, the claim limitation requiring the step of "providing in the sleeve a material which increases in rigidity" requires the act of supplying in a materially bounded object (*i.e.*, the sleeve) a material that is separate and distinct from the sleeve itself.

AGR relies on the following definitions of "provide," all of which it claims are consistent with the use of the word in claim 2: (1) "to make available;" or "to supply; to afford" (Webster's Twentieth); (2) "to furnish, supply, or equip;" "to afford or yield;" or "to prepare or procure beforehand (the latter being referred to as an "archaic" meaning)" (Random House); and (3) "to make preparation to meet a need;" or "to supply or make available" (Webster's Ninth). With regard to the term "in," AGR relies on the following dictionary definitions:(1) "contained or enclosed by, inside; within;" or "amidst; surrounded by;" or "into;" or "limited by the scope of" ("as, in my opinion"); "so as to form" ("as, arranged in curls"); "with; by; using" ("as, he paints in oil" and "written in English"); "made of" ("as, it was done in wood"); "by way of ("as, do this in my defense") (Webster's Twentieth); (2) "[w]ithin the confines of, inside;" or "[w]ithin the area covered by" (American Heritage Dict., p/ 663); (3) "used to indicate inclusion within space, a place or limits;" or "on the inside; within" (Random House); (4) "to or toward the inside,

esp. of a house or other building;" or "within a particular place;" or "that is located inside or within" (Webster's Ninth); (5) "by means of. with (written in pencil)"; or "used as a function word to indicate manner, state, or situation (alike in some respect) (left in a hurry)" (Webster's Intermediate Dictionary (1977)) (hereinafter "Webster's Intermediate"); and (6) "existing as a part, characteristic, or property of (in the works of Shaw);" or "made of a specified color, style or material;" or "for the purpose of (to run in pursuit);" or "by means of (speaking in whispers);" or "with regard or respect to (students vary in talent)" (Funk & Wagnalls Standard Desk Dictionary (1976)) (hereinafter "Funk & Wagnalls").

Cordis indicates that the sleeve of the Figure 9 embodiment in the specification has "inner and outer walls" (preferably made of Dacron or Teflon), and a separate fluid material is provided in the interior space between the inner and outer walls of the sleeve. (Description of the Preferred Embodiment, 6:11-14). Optionally, this material is provided in the sleeve just before the sleeve is introduced in the vessel, (*id.* at 6:35-40), but alternatively, it can be provided in the sleeve later, through a tube. (*Id.* at 7:7-10). Either way, the material that is being "provided in the sleeve" is separate from the sleeve itself according to Figure 9. However, this is a description of just one of the disclosed embodiments. It is merely one way that a material may be "provided in" the sleeve.

In another disclosed embodiment depicted in Figures. 1 through 7, Dr. Rockey describes a "sleeve unit" that "includes at least one, and preferably two, trailing hollowing filaments . connected thereto by bonding or other suitable means." (Description of the Preferred Embodiment, 3:45-47). Significantly, Rockey indicates that "[t]hese filaments ... may be made of the **same or similar material as the sheath [*i.e.*, sleeve]**." (*Id.* at 3:47-49) (emphasis added). The material of the sleeve, including its filaments, "is selected from a variety of known plastic and/or elastomeric substances." (*Id.* at 3:28-

30). In the remainder of the description of this embodiment, Dr. Rockey does not describe any separate material that is added to the sleeve unit to increase its rigidity. Thus, adding to the sleeve a separate and distinct material that increases in rigidity, which is admittedly what Dr. Rockey describes in Figure 9, is not essential to his invention. No other language or evidence in the Patent claims, the specification , or the file history restricts Dr. Rockey's invention by requiring that a foreign material be inserted into the sleeve to achieve rigidity. As demonstrated by the next step in claim 2 - "maintaining said balloon in an expanded condition in the vessel while said **sleeve increases in rigidity**" - all that is required is that **sleeve** increase in rigidity.

Accordingly, the claim construction of the phrase "providing in the sleeve a material" that is most consistent with the intrinsic record is: *to make available as apart or property of the sleeve itself, or to supply into the sleeve, a material.*

(b) "Increases in Rigidity After Expansion of Said Balloon"

The meaning of the term "increases" appears to be undisputed. Therefore, the following ordinary meaning of "increases" is adopted as consistent with the intrinsic record: *becomes progressively greater in size, amount, number or intensity.* (Webster's Ninth).

Cordis contends that "rigid" means "[d]eficient in or devoid of flexibility" (Webster's Ninth); or "stiff or unyielding; not pliant or flexible," or "firmly fixed or set" (Random House). Cordis' selected definition for "expansion" is "the act or process of expanding" (Webster's Ninth), and "after" means "following in time" (Webster's Third). Cordis' position is that under the ordinary meaning of the claim language, the material that is provided in the sleeve must increase in rigidity, *i.e.*, become more stiff and less flexible, and this increase in rigidity must take place *following* the act or process of expanding the balloon. Cordis argues that these definitions

are consistent with the surrounding text, because the next step in the claim 2 method involves the act of "maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity." According to Cordis, the language used in that step confirms that an increase in rigidity must take place following expansion of the balloon.

AGR has asked the Court to consider the following definitions of "rigidity": (1) "deficient in or devoid of flexibility;" or "appearing stiff and unyielding" (Webster's Ninth); (2) stiff or unyielding; not pliant or flexible; hard;" or "firmly fixed or set" (Random House); (3) "not easily bent; inflexible" ("as, *rigid* in death"); or "not moving; firmly fixed; set;" or "not deviating or relaxing; rigorous" ("as, *rigid* regulations") (Webster's Twentieth); (4) "lacking flexibility; stiff; hard; inflexibility set; unyielding" (Webster's Intermediate); (5) "resisting change of form; stiff, severe; fixed" (Funk & W agnalls); (6) "the quality or state of being rigid" (Webster's Ninth) (defining "rigidity").

AGR maintains that by arguing that this limitation requires an increase in rigidity after the full or complete expansion of the balloon, Cordis seeks to limit the claim terms. There are multiple dictionary definitions for the phrase "after," all of which are consistent with the use of the word in claim 2. For example, AGR offers that Webster's Twentieth defines "after" as" "later in time" and "according to the direction and influence of." AGR argues that this limitation is satisfied as long as there is some increase in rigidity after any expansion of the balloon, even if the doctor is still in the process of expanding the balloon. Cordis responds that this interpretation confuses "after" with "during."

The Patent, specification and file history have been examined to determine the meanings of the words "rigidity," "after" and "expansion" in context. There is no language or other evidence that requires that the balloon be fully expanded before the material in the sleeve starts to increase in rigidity. Dr.

Rockey describes, with respect to the preferred embodiment depicted in Figure 9, that "[t]he sleeve space 63 contains a fluid plastic material 66 which is caused to become solidified, **preferably to a semirigid state after the balloon has been expanded**." (Description of the Preferred Embodiment, 6:22-24) (emphasis added). He also wrote that "[t]he inflation pressure is maintained for a period sufficient for setting of the liquid 66 in the sleeve space 63 to become solidified into its semirigid state." (*Id.* at 6:52-54). And, he disclosed that "[a]fter the sleeve material has solidified into a semirigid structure, the balloon is deflated through the catheter." (*Id.* at 6:57-59). Finally, he wrote:

> It is contemplated that the catalyst for setting of the material 66 can be encapsulated and mixed with the base and caused to release from such encapsulation upon the pressure applied thereto by **expansion** of the balloon 50. Another alternative is to introduce the settable material 66, including mixed catalyst, into the space through the tube 64 after the sleeve has been manipulated into position.

(*Id.* at 7:3-10) (emphasis added).

At no point during this discussion does Dr. Rockey require that the balloon be fully expanded before **any** increase in rigidity takes place in the sleeve, especially considering that the trigger that causes the catalyst to begin the process of making the sleeve rigid is the first expansion of the balloon. Dr. Rockey specifically discusses how the sleeve material does not achieve a semirigid state until after the balloon has expanded (past tense), but this does not mean that there was no increase in rigidity while the balloon was expanding. Full expansion is not required for there to be an increase in rigidity. The progressive change in rigidity begins to occur as soon as the balloon begins to expand, which is what sets off the catalyst.

Dr. Rockey's use of the word "expansion" rather than "expanded" is telling. In describing the increase in rigidity, he refers to the process of "expansion" of the balloon, which is followed by the increase in rigidity of the sleeve material. In other parts of the specification , however, Dr. Rockey refers to a "fully expanded" sleeve (Brief Description of the Drawings, 3:9-11; 4:52). This suggests that had he meant "fully expanded," he would have said so.

The next step in the claim 2 method involves the act of "maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity." Contrary to Cordis' assertions, this step does not confirm that an increase in rigidity must take place following complete expansion of the balloon. The increase in rigidity takes place after the balloon begins to expand, and once the balloon has been fully expanded, the balloon is maintained in the inflated condition while the sleeve achieves the semirigid state required before the balloon may be removed. That is how Dr. Rockey described the process involved in his invention, and therefore, that is how the claims are to be interpreted.

The ordinary meanings of "rigidity" and "after" that are most consistent with the intrinsic record are as follows:

1. "Rigidity" means *the quality or state of being deficient in or devoid of flexibility, stiff and unyielding, hard, or firmly fixed or set.* (Webster's Ninth; Random House).

2. "After" means '*following in time.*" (Webster's Third).

3. "Expansion" means *"[t]he act or process of expanding.*" (Webster's Ninth).

Accordingly, the phrase "increases in rigidity after expansion of the balloon" requires that the *material contained in the sleeve or added to the sleeve during the procedure increase in rigidity after the balloon begins to expand.*

"Maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity"

Based on the preceding discussion of the meaning of the phrase "increases in rigidity after expansion of the balloon," the following ordinary meanings of the terms in this subsequent step in a sequence of procedures are the most consistent with the intrinsic record:

1. "Maintaining" means *keeping in an existing state.* (Webster's Ninth).

2. "Condition" means "*existing state.*" (Random House).

3. "While" means "*during the time that.*" (The American Heritage Dictionary, Second College Ed. (1982)).

Accordingly, this claim limitation requires *keeping the balloon in its expanded state after the balloon has fully expanded while the sleeve increases in rigidity to the point of attaining a semirigid state.*

"And thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated"

The following ordinary dictionary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

1. "Thereafter" means "*[a]fter that in time or sequence; afterwards.*" (Random House).

2. "Removing" means *moving from a place or position.* (Random House).

3. "Allowing" means *permitting something to happen or exist.* (Random House).

4. "Remain" means "*[t]o stay in the same place.*" (Webster's Ninth).

5. "Place" means *"[a] particular part of a surface or body."* (Webster's Ninth).

Accordingly, this limitation requires that, after the other five preceding steps of the method claim are performed, the user remove the catheter and the balloon from the vessel while contemporaneously leaving the sleeve in the same position in the area to be treated.

ii. Application of the Properly Construed Claim 2 to the Palmaz Stent Sold by Cordis

The first step of claim 2 of the '1,653 Patent requires "introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated." Based on the preceding construction, there are genuine issues of material fact precluding a summary judgment of non-infringement in favor of Cordis, including but not limited to: whether Cordis' stents are folded together compactly so that one part is laid over another part (*See, e.g.*, Leonard Depo., 94:3-10; 95:12-15; 96:1-4; 103:7-25; 104; 105; 108:24-25; 109:1-10) (the Cordis stent is "folded compactly" and doubled over with one part lying over another part); Puma Decl. ¶¶ 20-22 ("[I]ts [Cordis'] stents are not 'folded,' that is, no part of the stent is laid over another part. The stent is never doubled upon itself"); Widas Depo., 92:21-24; 93:1-4 (the Cordis stent is not "bent upon itself"); whether the Cordis stent encircles the balloon at or near the end of the catheter (Leonard Depo., 111:11-25; 224:10-20) (Cordis' stent is located near the end of the catheter); Puma Decl., ¶¶ 23-29) (Cordis' stent is not located at or near the end of the catheter; rather, it is located "at a distance"); Majercak Decl., ¶¶ 6-8 ("Cordis' stents and the balloon on which they are mounted are positioned so that the end of the catheter extends a distance beyond the stent and balloon.")); and whether the Cordis stent is a "sleeve." Although it seems unlikely that the Cordis stents could be a "sleeve" as disclosed by Rockey based on the undisputed fact that these stents have holes or openings, the technical experts

have not opined on whether the Cordis stents are nonetheless somehow capable of isolating body vessels from some materials that would normally come in contact with the vessels. Because no evidence has been presented on this issue, summary judgment is inappropriate.[13]

The second step requires "manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated." The third step envisions "inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the sleeve is radially expanded towards the wall of the vessel." The fourth step involves "providing in the sleeve a material which increases in rigidity after expansion of said balloon." The fifth step requires "maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity." Finally, the sixth step of claim 2 requires "thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated." As to all of these steps, and based on the Court's construction, there are issues of fact precluding summary judgment, including but limited to, whether the Cordis stent is a "sleeve" as that term has been construed by the Court.

c. The Doctrine of Equivalents

As a threshold issue, the undersigned addresses Cordis' position that AGR may not rely on the doctrine of equivalents to show infringement because the AGR experts have not provided sufficient evidence of infringement under the doctrine. Cordis argues that Dr. Leonard's Supplemental Report, and the Pope, Widas and Leonard declarations filed in response to Cordis' Motion for Summary Judgment, fail to address the basics of the doctrine of equivalents analysis. It is suggested

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[13] Moreover, Cordis has not moved for summary judgment based on the meaning of the term "sleeve."

that AGR's experts never compare the way in which the accused product and the sleeve of Dr. Rockey's invention perform any relevant function. In particular, Cordis contends that they never compare the way in which Cordis' stents and the sleeve of Dr. Rockey's invention increase in rigidity.

"Equivalence, in the patent law, is not a prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect." *Graver Tank*, 339 U.S. at 609; *National Presto Industries, Inc. v. The West Bend Company*, 76 F.3d 1185, 1191 (Fed. Cir. 1996). No specific formulation of evidence and argument is required to prove equivalence. *National Presto Industries, Inc.*, 76 F.3d at 1 191 (citations omitted); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997) ("In our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts.").

In appropriate cases, the function-way-result test offers guidance on the question of equivalence. Under this test, the fact finder determines whether the element in the accused device does substantially the same thing in substantially the same way to get substantially the same result as the claim limitation. *The Toro Company v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001). Another appropriate test is the "insubstantial differences" test. *Id.* Under this test, equivalency may be found where the difference in the accused device is facially "unimportant and insubstantial." *Id.* Similarly, an accused device may infringe where it lacks an insignificant function of a single claim limitation. *Id.* at 1371.

In order to prove infringement under the doctrine of equivalents, patentees must present evidence showing how

each claim limitation is present by a substantial equivalent in the accused device, and this must be shown through "particularized testimony and linking argument." *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996); *see HewlettPackard Co. v. Mustek Sys., Inc.*, 2003 WL 21804808, * 6 (Fed. Cir. Aug. 7. 2003) (citation omitted). The testimony must be presented on a limitation-by-limitation basis. That is, in order to provide the jury with "guiding charts when called upon to determine infringement under the doctrine [of equivalents]," the patentee should present "particularized testimony" of witnesses and "linking argument" by counsel. *Lear Siegler, Inc. v. Sealy Mattress Company of Michigan, Inc.*, 873 F.2d 1422, 1425-26 (Fed. Cir. 1989); *see Nestier Corp. v. Menasha Corp.*, 739 F.2d 1576, 1579-80 (Fed. Cir. 1984). While generalized testimony as to the overall similarity between the claim and accused device is insufficient, the patentee need only show "how the patented and the accused device were constructed and operated, overall as well as with respect to each claim element." *National Presto Industries, Inc.*, 76 F.3d 1185 at 1191. Conclusory assertions that an accused product performs the same function in the same way to achieve the same result are not enough. *Hewlett-Packard*, 2003 WL 2184808, at *6.

Cordis contends that Dr. Leonard's Supplemental Report fails to meet these basic requirements because it only offers conclusory assertions. For example, Cordis proffers that all Dr. Leonard does is parrot the tripartite test from *Graver Tank*, 339 U.S. at 608, by asserting that metal stents and polymer stents function in substantially the same way to achieve substantially the same result. Admittedly, mere recital of the *Graver Tank* mantra without more, is not enough to create a genuine issue of material fact as to whether an accused device infringes by equivalents. *See, e.g., Techsearch, L.L.C v. Intel Corp.*, 286 F.3d 1360, 1371-72 (Fed. Cir. 2002); *Moore US.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1113 (Fed. Cir. 2000). Moreover, Cordis argues, Dr.

Leonard also misses the mark by comparing a generic "polymer stent" with a stent made of 316L stainless steel. The proper comparison under the doctrine of equivalents would be a limitation-by-limitation comparison between the accused products and the sleeve of Dr. Rockey's invention.

Cordis' position is unavailing. A review of the expert testimony shows that AGR's experts have conducted an element-by-element analysis of claim 2 of the '1,653 Patent in their expert reports. In each instance where AGR's experts addressed the respective claim elements in their testimony they did not limit their opinions to literal infringement. For example, in his Supplemental Expert Report Dr. Leonard asserts, as to each disputed claim limitation, that the polymer sleeve patented by Dr. Rockey functions in the same way to achieve substantially the same result as the Cordis stainless steel stent. During the Pope deposition, Dr. Pope also indicated that some of the facts supporting the AGR experts' opinions regarding the doctrine of equivalents is that a stent made of stainless steel functions in substantially the same way to achieve substantially the same result as a stent made out of polymer. Thus, AGR's experts have testified that a stent made of stainless steel, which is plastically deformed during expansion, functions in substantially the same way to achieve substantially the same result, as a stent made by a polymer which undergoes polymerization and hardening upon expansion.

Most importantly, Dr. Leonard's Supplemental Report incorporates by reference his two earlier reports. In his initial report, Dr. Leonard details, on an element by element basis, how the Cordis stents are constructed and operate. In terms of the "way" the Cordis stents are used, Dr. Leonard relies upon the instructions provided with the medical sleeve. Dr. Leonard also explains in his first report how the methods set forth in claim 2 of the '1,653 Patent would be understood by one skilled in the art, how the Cordis stents are used and function,

the intended result of their use, and the way in which they achieve those results.

Specifically, in his initial report Dr. Leonard concludes that "to a reasonable degree of engineering certainty ... based upon my review of the Accused Products [Cordis' stents] and the method by which those products are specified for their use as described in the instructions provided, and with the devices furnished for their placement, . . . the accused device meets every limitation of claim 2 of the '1,653 Patent." (Leonard Expert Report, 135). On an element-by-element basis, Dr. Leonard further explains how each step of the Rockey method claim is practiced in the Cordis stents. In terms of their function, Dr. Leonard explains that the Cordis stents are "used for introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve or stent encircling the balloon on its end into a vessel at a point remote from the area to be treated. For instance, the coronary stent is inserted in the femoral artery which is remote from the coronary arteries, which is the area to be treated." Further, the Cordis stents, like Rockey's method claim, are designed to "resist compressive stresses that tend to collapse" stents and "to allow the sleeve and stent to remain in place in the area to be treated." Dr. Leonard explains that the way this is accomplished is by inserting the Cordis stents into a vessel at a point remote from the area to be treated, and then manipulating the catheter axially along the vessel causing the balloon and stent to enter the area to be treated. He further explains that the balloon is then inflated by introducing fluid under pressure into the balloon through a tube of the catheter in a manner in which the Cordis stent surrounding the balloon is radially expanded toward the wall of the vessel.

After being expanded in the area to be treated, the "way" in which the Cordis stents are able to remain in place and resist compressive stresses is that they "have a material in the sleeve which increases in rigidity after expansion of the balloon." In particular, Dr. Leonard explains that "the stainless

steel utilized in the stent or sleeve is internally strengthened by plastic deformation within each of its elements," and "is also strengthened in its entirety by reorientation of its elements with respect to each other from an internal, predominantly axial orientation to a final, more circumferential position." Finally, the method for using the Cordis stents requires that the balloon and catheter be removed, leaving the stent in place in the area to be treated.

Dr. Leonard also states in his initial report that all of the referenced methods for using the Cordis stents are within the limitations of claim 2 of the '1,653 Patent. He explains or interprets claim 2 of the '1,653 Patent. In particular, if claim 2 of the '1,653 Patent were construed to be limited to polymer stents, Dr. Leonard explains that a polymer stent functions in substantially the same way to achieve substantially the same result as the Cordis stents made of 316L stainless steel. Dr. Leonard further details, on an element by element basis, that there are insubstantial differences between polymer and metal stents in their "functions, ways and results." For example, both stents employ the same "way" of resisting compressive forces after expansion in the area to be treated by having a material in the stent which increases in rigidity after expansion of the balloon. The insubstantial difference is that the material in a polymer stent is a polymer and the material in the Cordis stents is 316L stainless steel, both of which nonetheless share the physical property of increasing in rigidity after expansion of the balloon.

Therefore, AGR's experts, particularly Dr. Leonard and Dr. Pope, have provided testimony supporting a finding of that all six claim limitations of claim 2 are present in the Cordis stent. They have testified that the Cordis stent and the Rockey sleeve **function** in the same **way**, and/or their differences are insubstantial, because both are small and compact enough to be inserted along with a catheter and a balloon (step one of claim 2) and manipulated into a body vessel (step two of claim 2), after which the balloon is inflated, causing

the stent or sleeve, which is made of or supplied with a material that increases in rigidity after the balloon begins to expand (step four of claim 2), to expand towards the wall of the vessel (step three of claim 2), and the balloon is maintained in an expanded condition until the sleeve or stent is sufficiently rigid (step five of claim 2), and finally the balloon and catheter are removed from the vessel while the stent or sleeve is left in place (step six of claim 2), causing the vessel to remain open (the **result** of both inventions). Dr. Laird, on the other hand, applies the reverse doctrine of equivalents and finds that the two inventions do not function in the same way to achieve substantially the same result because the stainless steel in the Cordis stents increase in rigidity " in an entirely different way" than the material described in the '1,653 Patent. (Laird Expert Report, p. 16-17).

Thus, in accordance with Rule 56(c), Fed. R. Civ. P., there is a genuine issue of material fact precluding summary judgment on the issue of whether the Palmaz stent and the Rockey sleeve function in substantially the same way to achieve substantially the same result, or whether the differences between them are insubstantial, under the doctrine of equivalents.

d. *The Validity of the Rockey '1,653 Patent*

AGR seeks a construction of the ' 1,653 Patent that would expand the scope of Dr. Rockey's Patent to cover balloon-expandable metal stents, such as the Palmaz and Palmaz-Schatz stents. Cordis responds that if the Rockey Patents were construed to cover balloon-expandable metal stents, then the prior inventive work of Dr. Palmaz would invalidate the '1,653 Patent under 35 U.S.C. § 102 (g). *See Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001) ("[I]f a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent."). Cordis has the burden of proof on the issue of invalidity, and it must pre-

sent clear and convincing evidence in order to prevail on this issue. *See, e.g., Magnivision, Inc. v. The Bonneau Co.*, 115 F.3d 956, 958 (Fed. Cir. 1997) ("The presumption [of patent validity] operates by placing the burden of proving invalidity on the person attacking the patent, who must prove invalidity by clear and convincing evidence.") (citing 35 U.S.C. § 282). The ultimate burden of providing invalidity remains with the challenger throughout the litigation. *Id.*

Cordis has not sought a summary judgment on the invalidity defense, but it has raised the issue in its briefs in support of summary judgment. The evidence presented in connection with summary judgment, including the expert testimony, raises genuine issues of material fact for trial regarding the validity of the Rockey Patents, including but not limited to: (1) the date that Dr. Palmaz conceived of and reduced to practice, according to the provisions of 35 U.S.C. § 102(g), the balloon-expandable metal stents sold by Cordis; (2) the date that Dr. Rockey conceived of and reduced to practice, according to the provisions of 35 U.S.C. § 102(g), the device claimed in the ' 1,653 Patent; and (3) the "priority date" that applies to the claims of Dr. Rockey's '1,653 Patent corresponding to the proper application filing date for the Patent under 35 U.S.C §§ 112, 120, including the related issue of whether each of the claims in the '1,653 Patent were disclosed in the June 2, 1978 '010 Application, which is the earlier filing date that AGR seeks to apply. In other words, even assuming that Dr. Palmaz's stents contain all of the claim limitations of claim 2 of the Rockey '1,653 Patent, there are remaining factual disputes regarding who invented the subject matter, *i.e.*, balloon-expandable metal stents, first. *See, e.g., T & T Geotechnical, Inc. v. Union Pacific Res. Co.*, 944 F. Supp. 1317,1320-21 (N.D. Tex. 1996) (denying summary judgment because evidence raised genuine issues of material fact on issue of patent validity); *P.A.T. Co. v. Ultrak, Inc.*, 948 F. Supp. 1506, 1515-16 (D. Kan. 1996); *Acoustiflex Corp. v. Owens-Corning Fiberglas Corp.*, 572 F. Supp. 936,

937 (N.D. Ill. 1983) ("[A] patent case is not ripe for summary judgment on the issues of validity or enforceability where the technical aspects are not readily comprehensible by one unskilled in the art, where the record is inadequate to decide the issue, where there is a need for expert testimony, where the expert testimony submitted is conflicting, or where there is some other genuine issue of credibility on a motion for summary judgment."). *And see H.B. Fuller Co. v. National Starch & Chem. Corp.*, 595 F. Supp. 622, 624 (D. Del. 1984) (finding issues of fact precluding summary judgment regarding whether patent allegedly infringed could be credited with earlier filing date of a parent application).

e. *The Statute of Limitations*

This action was commenced on July 1, 2002. Cordis argues that all of AGR's claims are barred under the Florida five-year statute of limitations for breach of contract actions, to the extent that AGR seeks damages for sales of Cordis' stents prior to July 1, 1997. The parties agree that the five-year statute of limitations in Section 95.11(b)(2) of the Florida Statutes applies here.

Under Florida law, where a contract requires payments in installments, the applicable statute of limitations ordinarily starts to run on the date each payment becomes due. *See, e.g., Isaacs v. Deutsch*, 80 So.2d 657, 660 (Fla. 1955); *Holiday Furniture Factory Outlet Corp. v. State of Florida, Dep 't of Corr.*, 852 So.2d 926, 928 (Fla. 151 D CA 2 003); *Bishop v. State of Florida, Div. of Retirement*, 413 So.2d 776, 778 (Fla. V DCA 1982); *Central Home Trust Co. of Elizabeth v. Lippincott*, 392 So.2d 931, 933 (Fla. 5th DCA 1980). A contract that contemplates payments to be made at different times is analogous to an installment payment contract. *Hannett v. Bryan*, 640 So.2d 203, 204 (Fla. 4th DCA 1994). Where the installment contract contains an optional acceleration clause, the statute of limitations may commence running earlier on payments not yet due if the holder exercises its right to accel-

erate the total debt because of default. *Central Home*, 391 So.2d at 933. In that situation, "the entire debt does not become due on the mere default of payment; rather, it becomes due when the creditor takes affirmative action to alert the debtor that he has exercised his option to accelerate." *Greene v. Bursey*, 733 So.2d 1111, 1115 (Fla. 4th DCA 1999).[14]

In cases analogous to this one in which a patent licensor has brought action against a licensee for breach of contract in connection with a licensee's failure to pay royalties under a license agreement, courts have found that because the royalty payments were due at different times, a separate and distinct cause of action accrued for each payment as it became due, and the statute of limitations started to run on each payment due date. *See Moore v. Medtronic, Inc.*, 2001 WL 1636248, *3 (D. Minn. 2001) (applying Minnesota law and finding that royalties that accrued, *i.e.*, that were due, prior to six years (the applicable statute of limitations period) before filing of complaint were barred); *Refac Financial Corp v. Patlex Corp.*, 912 F. Supp. 159, 162-63 (E.D. Pa. 1996) (applying Pennsylvania law); *H.M Chase Corp. v. Idaho Potato Processors, Inc.*, 529 P.2d 1270, 1272 (Idaho 1974) (applying Idaho law; license agreement called for installment royalty payments to be paid on the tenth day of each month for the production of the preceding month). In *Refac*, the court rejected the argument that the license agreement was a continuing contract such that the statute of limitations did not begin to run until the contract was terminated, finding that the alleged breach (royalty deductions taken by patent licensee) had admittedly occurred, so that the statute had begun to run as to each deduction when taken. *Refac*, 912 F. Supp. at 162-63.

Assuming the jury finds Cordis' stents are covered by the Rockey Patents and that, therefore, the License Agreement required Cordis to make royalty payments to AGR, Cordis is correct that each royalty payment is a severable portion of the

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[14] The License Agreement does not contain such an acceleration clause.

contract which starts the statute of limitations running. Cordis and AGR agree that royalty payments that became due on or after July 1, 1997 are not time-barred. This would include royalties on sales made before July 1, 1997, as long as those royalties became due on or after July 1, 1997. However, AGR is barred by the five-year statute of limitations from seeking damages for royalties that became due prior to July 1, 1997.[15]

The undersigned notes that, under the License Agreement, royalties are not due every three months, but every three months following Cordis' first $20 million in sales of products covered by the Rockey Patents, defined in the License Agreement as the "Royalty Date." There are genuine issues of fact as to the exact date Cordis achieved $20 million in sales of stents covered by Rockey Patents (if this even occurred), and the subsequent dates that each royalty payment became due.

3. Breach of Duty to Exploit (Count II)

Count II alleges that the exclusive licensing provision of the License Agreement subjects Cordis to an implied duty and obligation to use its "best efforts" to perform under the contract, and despite that obligation, Cordis has failed to properly commercialize the inventions disclosed and claimed in the Rockey Patents. In other words, AGR alleges that Cordis breached an "implied duty" by not developing **some** product that **would** practice the Rockey Patents and therefore require the payment of royalties. Cordis argues that AGR is essen-

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[15] The Court rejects AGR's argument that the statute of limitations has not begun to run under the continuing breach doctrine, which provides that on a contract requiring serial performance by the parties, accrual of a breach of contract cause of action commences upon the occurrence of the last breach or the termination of the contract. AGR maintains that the License Agreement is still in force and has not been terminated. The "continuing breach" doctrine that AGR relies on only applies to contracts calling for a single, continuous performance; it does not apply to contracts like the License Agreement that call for performance (*i.e.*, royalty payments) in separate and distinct installments.

tially trying to rewrite the License Agreement because the Agreement does not contain any provision obligating Cordis to try to develop a Licensed Product.

There is no explicit "best efforts" clause in the License Agreement. Cordis cites to Florida law holding that parties are not entitled to alter or add negotiated obligations defined in contracts by reading implied duties into an agreement. Under Florida law, the governing law under the License Agreement, an action for breach of an implied contractual duty cannot be maintained "in the absence of breach of an express contractual provision," and there is no express contractual provision obligating Cordis to develop a royalty-generating product. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1318 (11th Cir. 1999). While AGR refers to representations allegedly made by Cordis during negotiations prior to execution of the Agreement, those alleged representations regarding anticipated income from commercialization of the Rockey technology, etc., may not be considered because they are barred by the merger clause in the License Agreement.

Furthermore, where a license agreement contains a merger or integration clause and requires a substantial advance royalty payment, courts have consistently refused to read an "implied duty to exploit" into the agreement, and have granted or affirmed summary judgment dismissing claims alleging breach of an "implied duty to exploit." *See, e.g., Permanence Corp. v. Kennametal, Inc.*, 908 F.2d 98 (6th Cir. 1990) (finding no implied obligation on the part of licensee under patent license agreement to use its best efforts to market product embodying patent, so as to maximize licensor's royalty income; licensee had paid licensor a $150,000 fee and a $100,000 advance against royalties, thus providing consideration for agreement other than its best efforts undertaking, and agreement contained merger clause); B*eraha v. Baxter Health Care Corp.*, 956 F.2d 1436, 1442 (7th Cir. 1992) (court would not provide by implication a "best efforts" clause in exclusive patent license agreement where licensor negotiated increase

in advance royalties and royalty payments, and agreement contained merger clause).[16] The substantial advance royalty payment of $2 million paid by Cordis to AGR provided AGR with bargained-for consideration. (Cordis Statement of Facts, p. 2; AGR's Response to Cordis' Statement of Facts, p. 10 (AGR admits that Cordis made a $2 million advance royalty payment to AGR)). Paragraph 3.2 of the License Agreement provides that the $2 million payment "shall be considered pre-paid royalties for the Advance Sales."

It is unnecessary to imply a duty to use best efforts to exploit technology that arises from a patent license agreement like the License Agreement at issue because (1) AGR refers to no express provision of contract the on which it relies - no "best efforts" clause; and (2) there was a substantial advance payment of royalties to AGR. Thus, summary judgment is appropriate on this Count.

4. Breach of Duty of Good Faith and Fair Dealing (Count III)

AGR sues Cordis in Count III for breach of the implied duty of good faith and fair dealing in connection with the License Agreement as a result of Cordis' failure to extend the life of the Rockey Patents. The express provision of the License Agreement that concerns extensions of the term of the Rockey Patents states that "Cordis **may** attempt to obtain a

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[16] *See also HML Corp. v. General Foods Corp.*, 365 F.2d 77 (3d. Cir. 1966) (finding no best efforts obligation where there was substantial cash payment required in exclusive licensing contract); *Triple Point Tech, Inc. v. D.NL. Risk Mgmt., Inc.*, 2000 WL 1236227, *34 (D.N.J. 2000); *Para-Data Computer Networks, Inc. v. Telebit Corp.*, 830 F. Supp. 1001, 1006 (E.D. Mich. 1993) (finding no duty to use best efforts implied in exclusive licensing contract that included $1 million up-front payment and additional $1 million in prepaid royalties); *Kardios Systems Corp. v. The Perkin-Elmer Corp.*, 645 F. Supp. 506, 509 (D. Md. 1986) (finding no best effort obligation due to upfront payments of almost $200,000); *Vacuum Concrete Corp. v. American Mach. & Foundry Co.*, 321 F. Supp. 771 (S.D.N.Y. 1971).

term extension for the Patents **if** Cordis determines that the likely term extension will result in an additional amount of Running Royalties which exceeds the reasonable cost of obtaining such extension." (License Agreement, § 14.9) (emphasis added). This language gives Cordis substantial, if not complete, discretion in deciding whether to seek a term extension.

As Cordis points out, in attempting to show that Cordis has unreasonably exercised its discretion and thereby breached the implied covenant of good faith and fair dealing, AGR has a heavy burden. Admittedly, the implied covenant of good faith and fair dealing is a part of every contract under Florida law. *Ernie Haire Ford, Inc. v. Motor Co.*, 260 F.3d 1285, 1291 (11th Cir. 2001) (citing *Burger King*,169 F.3d at 1315). The implied covenant cannot override an express contractual term, *id.* (citing *Ins. Concepts & Design, Inc. v. Healthplan Servs., Inc.*, 785 So.2d 1232, 1234 (Fla. 4th DCA 2001)), but "[w]ith the implied covenant, one party cannot **capriciously** exercise discretion accorded it under a contract so as to thwart the contracting parties' **reasonable expectations.**" *Id.* (emphasis added) (citing *Sepe v. City of Safety Harbor*, 761 So.2d 1182, 1185 (Fla. 2d DCA 2000) (holding that, even where one party has "sole discretion" under a contract, that party, in exercising its discretion, must act in good faith and in accordance with the contracting parties' expectations); *Cox v. CSX Intermodal, Inc.*, 732 So.2d 1092, 1097-98 (Fla. 1st DCA 1999) (same)). AGR's burden is to show that no reasonable party would have made the same discretionary decision Cordis made. *See, e.g., Sepe*, 761 So.2d at 1185.

In applying the foregoing principles, courts in Florida and in this Circuit have focused on whether the discretionary decision frustrated the central purpose of the contract. Notwithstanding the broad discretion afforded in the underlying contract, one Florida appellate court reversed a summary judgment in favor of the defendant, finding that there were issues of fact as to whether the manner in which the defendant exer-

cised its discretion violated the implied duty of good faith, fair dealing and commercial reasonableness. *Cox*, 732 So.2d at 1097-98. The Eleventh Circuit reviewed the *Cox* decision and noted that "[t]he central purpose of the contract in Cox was the hauling of freight. By failing to assign freight [the discretionary act at issue], CSX frustrated that purpose and the reasonable expectation of the parties." *Ford*, 260 F.3d at 1292. The Eleventh Circuit then proceeded to distinguish the facts in *Ford* from the facts in *Cox* as follows:

> Here, however, the central purpose of the Dealership Agreement was to sell cars, not to relocate the dealership. In disapproving the relocation, Appellee did not preclude Appellants from selling cars. Instead, based on 'its best judgment,' Appellee forbid [sic] the relocation of the dealership to a site where, granted, Appellants would have financially benefitted. Although Appellee's decision was not in Appellants' best interests, it was neither capricious nor in contravention of the parties' reasonable expectations.

Id. at 1292; *see also Burger King Corp. v. Ashland Equities, Inc.*, 217 F.Supp.2d 1266, 1275-77 (S.D. Fla. 2002) (granting summary judgment in favor of franchisor on a claim for breach of the covenant of good faith and fair dealing; holding that franchisor's decision not to approve a franchise sale by the franchisees, which was within the franchisor's complete discretion, did not violate the implied covenant because the central purpose of the franchise agreement was the sale of the franchisor's products, not the sale or transfer of restaurants, and the franchisor's decision was not capricious as the prospective purchaser recommended by franchisees did not satisfy the managerial and financial requirements set forth in the agreement).

Here, Cordis' decision not to extend the term of the Rockey Patents is inextricably intertwined with the central purpose of the License Agreement, *i.e.*, providing Cordis with

an exclusive license to manufacture, use and sell the products covered by the Rockey Patents in exchange for Cordis' payment of royalties. AGR alleges that "[s]uch an extension would have resulted in a longer period of time during which Cordis would be obligated to continue to pay the Running Royalties." AGR's assertion is supported by paragraph 7.1 of the License Agreement, which provides that "[u]nless sooner terminated ..., the term of this Agreement shall be to the end of the term for the last patent to expire of any of the Patents." The determination of whether Cordis is obligated to pay royalties on the accused products is one that will be made by a jury in resolving Count I; and, it appears, assuming *arguendo* that Cordis is obligated to pay royalties on the products at issue, that an extension of the term of the Rockey Patents would have a direct impact on the rights of the parties under the License Agreement.

However, the evidence in the record supports Cordis' assertion that it could not have obtained an extension of the Rockey '1,653 Patent under 35 U.S.C. § 156, and therefore, Cordis' decision not to seek an extension of the Rockey Patent was neither capricious nor in contravention of the reasonable expectation of the parties. Only the first product approved by the "FDA" and covered by the '1,653 Patent (which AGR contends was the Palmaz balloon-expandable stent that received the required approval in 1991), could have been used to obtain an extension,[17] and that approval was the basis for a patent extension of the Palmaz '3,665 Patent in May, 1993. (Reply Appendix in Support of Cordis' Motion for Summary Judgment, Exh. 57 & 58). Only a single patent is entitled to an extension based on an approved product, and

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[17] Title 36, Section 156(a)(5), United States Code, provides that the term of a patent shall be extended from the original expiration date of the patent if "the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A).

an application for an extension must be filed within sixty (60) days of approval. 35 U.S.C. §§ 156(c)(4), (d)(1). Because the Palmaz Patent had already been extended, and more than 60 days had passed between the time of approval by the FDA for the Palmaz product (1991) and the License Agreement (1995) and Cordis' merger with J & J (1996), the record reflects that Cordis could not have legally obtained an extension of the Rockey ' 1,653 Patent. Under the circumstances, it cannot be said that no reasonable party would have made the same decision Cordis made. Accordingly, summary judgment is also appropriate on Count II.

IV. CONCLUSION

For all the foregoing reasons, it is

ORDERED AND ADJUDGED as follows:

1. AGR's Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents **(D.E. 102)** is **DENIED**.

2. AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony **(D.E. 103)** is **DENIED**.

3. AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph **Puma (D.E. 104)** is **DENIED**.

4. AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony **(D.E. 105)** is **GRANTED**.

5. AGR's Motion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection **(D.E. 106)** is **DENIED**.

6. Cordis' Motion *in Limine* to Exclude Parol Evidence **(D.E. 108)** is **GRANTED**.

7. Cordis' Motion *in Limine* to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on Products

that Practice the Rockey Patents "In Whole Or In Part" **(D.E. 108)** is **GRANTED**.

8. Cordis' Motion *in Limine* to Exclude or Limit the Testimony of AGR's Patent Law Experts **(D.E. 108)** is **GRANTED** in part.

9. Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents **(D.E. 108)** is **DENIED**.

10. Cordis' Motion *in Limine* to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert* **(D.E. 108)** is **DENIED**.

11. Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985 for Claim 2 of the '1,653 Patent **(D.E. 121)** is **DENIED**.

12. Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard **(D.E. 150)** is **DENIED**.

13. Cordis' Motion for Summary Judgment **(D.E 45)** is **GRANTED** in part. Summary judgment is hereby **ENTERED** in favor of Cordis, and against AGR, on Counts II and III.

14. Cordis' Motion for Construction of Terms in the Claims of the Rockey '1,653 Patent **(D.E. 107)** is **GRANTED** in part.

It is further **ORDERED AND ADJUDGED** that this matter is set for a status conference on Thursday, **January 8, 2004, at 10:00 a.m.** The parties may set up a multi-party telephone conference call with chambers in lieu of appearing in person.

DONE AND ORDERED in Chambers at Miami, Miami-Dade County, Florida, this 5 day of January, 2004.

s/ Cecilia M. Altonaga

CECILIA M. ALTONAGA
UNITED STATES DISTRICT JUDGE

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APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

Case No: 02-22555-CIV-ALTONAGA/Bandstra

ARLAINE & GINA ROCKEY, INC.,

Plaintiff,

vs.

CORDIS CORPORATION,

Defendant.

_____/

AMENDED ORDER ON PENDING MOTIONS[1]

THIS CAUSE came before the Court upon the following pending motions: (1) Plaintiff, Arlaine & Gina Rockey, Inc.'s ("AGR") Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents **(D.E. 102)**; (2) AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony **(D.E. 103)**; (3) AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph Puma **(D.E. 104)**; (4) AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony **(D.E. 105)**; (5) AGR's Mo-

[1] This Order amends the "Order on Pending Motions, and Setting Status Conference" that was entered on January 5, 2004. It does so upon a careful consideration of Defendant, Cordis Corporation's Motion for Reconsideration **(D.E. 165)**, filed on January 20, 2004, and the parties' arguments heard on March 8, 2004. The Motion **(D.E. 165)** is **GRANTED** as indicated in this Amended order on Pending Motions.

tion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection **(D.E. 106)**; (6) Defendant, Cordis Corporation's ("Cordis") Motions *in Limine* to Exclude Parol Evidence, to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on Products that Practice the Rockey Patents "In Whole Or In Part," to Exclude or Limit the Testimony of AGR's Patent Law Experts, to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents, and to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert* **(D.E. 108)**; (7) Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985 for Claim 2 of the '1,653 Patent **(D.E. 121)**; (8) Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard **(D.E. 150)**; (9) Cordis' Motion for Summary Judgment **(D.E 45)**; and (10) Cordis' Motion for Construction of Terms in the Claims of the Rockey '1,653 Patent **(D.E. 107)**. The Court has reviewed the Motions, the response and reply memoranda, and the pertinent portions of the record. The Court also heard oral argument on the Motions on August 28, 2003 and October 31, 2003.

I. FACTUAL BACKGROUND[2]

A. THE PARTIES

During the late 1970's, Dr. Arthur G. Rockey ("Dr. Rockey"), a podiatrist, began experimenting with methods of treating various problems with body cavities, namely blood vessels and the gastrointestinal tract. He developed a number of medical inventions, and the U. S. Patent and Trademark Office ("PTO") issued Dr. Rockey three patents, including United States Patent No. 4,501,264, issued on February 26,

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[2] The facts are taken from the Statements of Facts submitted by the parties and from the documentary and testimonial evidence before the Court, and are undisputed unless otherwise noted.

1985 (the "'1,264 Patent"); United States Patent No. 4,641,653, issued on February 10, 1987 (the "'**1,653 Patent**"); and United States Patent No. 4,763,653, issued on August 16, 1988 (the "'3,653 Patent") (collectively the "Rockey Patents"). All three patents concern methods of using a medical sleeve. Dr. Rockey passed away in 1987, one year before his third patent was issued.

AGR is a Wyoming corporation formed in 1992 to market and commercially exploit Dr. Rockey's inventions. The shareholders of AGR are Dr. Rockey's two daughters, attorneys Arlaine Rockey and Gina Rockey Collias, and his widow. AGR owns the three U.S. patents issued to Dr. Rockey.

Cordis is a Florida corporation with its headquarters in Miami Lakes, Florida. It was founded in 1959, and Johnson & Johnson ("J & J") acquired Cordis in February 1996. Cordis is a leader in marketing stents for use in coronary arteries and other body passageways. As a result of the acquisition, a J & J subsidiary that had been selling metal stents became a Cordis affiliate. That subsidiary was merged into Cordis, and thus Cordis has been selling balloon-expandable metal stents based on inventions by Dr. Julio Palmaz ("Dr. Palmaz") and Dr. Richard Schatz ("Dr. Schatz") since 1996.

B. THE ROCKEY '1,653 PATENT AND ITS PROSECUTION HISTORY

Dr. Rockey filed his first application for a "Medical Sleeve" on June 2, 1978, and it was assigned U.S. Patent Application No. 912,010 (the "'010 Application"). The '010 Application disclosed two embodiments of an invention for a medical sleeve, one for a stomach sleeve and the other for a graft in the aorta or common iliac arteries. The '010 Application did not mature into an issued patent and was later abandoned. However, Application Serial No. 216,989 (the '989 Application") was filed on December 16, 1980 as a continua-

tion-in-part of the '010 Application and became the '1,264 Patent in 1985.

Subsequently, Application Serial No. 702,828, which was filed on February 19, 1985, became the '1,653 Patent on February 10, 1987. The '1,653 Patent application added a new figure (Figure 9) and also added new text that describes the embodiment that is depicted in Fig. 9. Figure 9 shows a balloon catheter used to deliver a sleeve to a treatment site. Pressurized fluid travels through the catheter to the balloon and is used to inflate the balloon. The balloon and catheter are then removed from the body, leaving the sleeve in place in the area to be treated.

In this lawsuit, AGR contends that the Palmaz stent, the Palmaz-Schatz stent and more recent stents sold by Cordis are all covered by **one** claim of **one** licensed Rockey Patent - claim 2 of the '1,653 Patent. Claim 2 of the Patent is a method claim that describes a method of using a sleeve with specified characteristics to treat an area of a body vessel. The claimed method includes six action steps. Claim 2 reads in its entirety as follows:

> 2. A method of treating an area of a body vessel, comprising the steps of:
>
> [a] introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated;
>
> [b] manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated;
>
> [c] inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel;

[d] providing in the sleeve a material which increases in rigidity after expansion of said balloon;

[e] maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity; and

[f] thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated.

Dr. Rockey's final application, Application Serial No. 11,335, was filed on February 5, 1987 and issued on August 16, 1988 as the '3,653 Patent. All three patents describe a method and article for medical diagnosis and/or treatment of body disorders, comprising a sleeve unit that may be inserted into a natural body vessel to isolate material flowing into the vessel from direct contact with the interior surface of the vessel. The first two patents, the '1,264 Patent and the '1,653 Patent, specifically address the treatment of obesity.

Cordis' position is that Dr. Rockey's earliest possible "priority date" for the invention disclosed in the '1,653 Patent is the date when the application for the '1,653 Patent was filed -- February 19, 1985. AGR argues that the June 2, 1978 filing date of the '010 Application is the "priority date" that should be applied to the claims of the '1,653 Patent. There is also conflicting evidence regarding whether each of the limitations of claim 2 of the '1,653 Patent was disclosed in the previous '010 Application, as required for the earlier filing date to apply. The experts differ as to whether the '010 Application and the '989 Application disclose the steps described in claim 2 of the '1,653 Patent of **removing** the catheter and balloon from the vessel at the end of the procedure, and providing in the sleeve a material that increases in rigidity after expansion of the balloon.

C. THE PALMAZ, PALMAZ-SCHATZ AND OTHER STENTS SOLD BY CORDIS

Until 1994, the main treatment for opening up blocked arteries was balloon angioplasty. Angioplasty had serious drawbacks, and researchers were looking for a better treatment. Those researchers included Dr. Palmaz and his colleague, Dr. Schatz.

At the heart of this case is the issue of who is the true and first inventor of the balloon-expandable stent. Sometime in the late 1970's or early to mid 1980's, Dr. Palmaz began work on what was to become known as the Palmaz or the Palmaz-Schatz balloon-expandable stent. Dr. Palmaz allegedly conceived of his invention sometime between 1978 and 1984. He has testified that, working in his garage in the late 1970's, he invented the balloon-expandable stent. Back in 1980, Dr. Palmaz had described his invention in detail in a written "monograph." And, in the early 1980's, Dr. Palmaz made prototype stents and successfully implanted them in dogs.

Dr. Palmaz has testified that he conceived of his invention after attending a lecture by Dr. Andreas Gruntzig, who is known as the father of balloon angioplasty. Dr. Gruntzig explained his idea of balloon angioplasty as a method of treating vascular disease. Dr. Gruntzig also described some of the complications associated with using angioplasty as a treatment. At his lecture, Dr. Gruntzig performed one of the first live demonstrations of angioplasty in the United States, and many of the complications that Dr. Gruntzig described occurred. Upon hearing about and seeing these complications, Dr. Palmaz claims that he conceived the idea of using a scaffolding that would be delivered on and expanded by an angioplasty balloon, and would be left behind to support the vessel wall, ameliorating the dire complications of angioplasty. Dr. Palmaz then worked diligently on his invention for

the next several years, leading to a successful implantation in an animal in 1984.

The facts provided by Dr. Palmaz relating to his conception date are all disputed by AGR. There is some evidence, however, that corroborates Dr. Palmaz's version of events, including Dr. Palmaz's copy of the program from Dr. Gruntzig's lecture with Dr. Palmaz's handwritten notations, hotel and airline receipts for Dr. Palmaz's trip to attend the lecture, receipts for materials that Dr. Palmaz ordered for the purpose of making prototypes of his invention, written monographs in which Dr. Palmaz explains his research, correspondence showing Dr. Palmaz's attempts to interest companies in his inventions, and x-rays of successful implants of Dr. Palmaz's stent in dogs.

Dr. Palmaz filed his first patent application, Application Serial No. 796,009 (the "796,009 Application"), for his balloon-expandable metal stent on November 7, 1985, which issued as U.S. Patent No. 4,733,665 (the "Palmaz '3,665 Patent"). The Palmaz '3,665 Patent describes an "expandable intraluminal vascular graft [that] is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel." Dr. Palmaz was issued a second patent for a related invention on April 26, 1988, which was assigned U.S. Patent No. 4,739,762 (the "Palmaz '9,762 Patent"). Dr. Palmaz filed the application for the '9,762 Patent, which was a continuation-in-part application of the earlier 796,009 Application, on November 3, 1986, and it was assigned Application Serial No. 923,798. On March 29, 1988, the PTO extended the patent term of the Palmaz '3,665 Patent for 182 days pursuant to an application made by the Patent owner under 35 U.S.C. § 156. Palmaz achieved his first approval from the Food and Drug Administration ("FDA") for a balloon-expandable stent on September 27, 1991.

On February 19, 1991, Dr. Schatz filed his first patent application for an "expandable intraluminal graft," Application No. 657,296. It was issued on March 23, 1993 as U.S. Patent No. 5,195,984. Dr. Schatz's second patent, U.S. Patent No. 5,800,516, for a "deployable and retrievable shape memory stent/tube and method," issued on September 1, 1998, and derived from Application No. 693,708 filed on August 8, 1996.

Other patents for stents sold by Cordis include: (1) the "deployable and retrievable shape memory stent/tube and method," U.S. Patent No. 5,800,516, issued on September 1, 1998, based on Application No. 693,708 filed on August 8, 1996 by inventor, Michael J. Fine; (2) the "method for making a multi-laminate stent having super elastic articulated sections," U.S. Patent No. 6,425,855 B2, issued on July 30, 2002, based on Application No. 09/852,094 filed on May 9, 2001 by inventor, Charles V. Tomonto; and (3) the "covered expanding mesh stent," U.S. Patent No. 5,968,070, issued on October 19, 1999, based on Application No. 08/909,520 filed on August 11, 1997 by inventor, Robert S. Bley.[3] The products patented by the Palmaz and Schatz Patents and the Rockey '1,653 Patent are the inventions at issue in this litigation, although the other patents and inventions are also considered.

The Palmaz and Schatz stents, and a more recent BX Velocity stent sold by Cordis, are small lattice-like structures that are made of a single material, medical grade stainless steel, *i.e.* 316L stainless steel. (Declaration of David C. Majercak ("Majercak Decl."), ¶ 3). Cordis does not provide a separate material in the stent that is separate and distinct from the stent itself, and physicians also do not provide in Cordis' balloon-expandable stents a material that is separate and distinct from the stents themselves. (Majercak Decl., ¶ 11; Dec-

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[3] All of these stents, sold By Cordis since May 15, 1995, are referred to in this Order as "Cordis' stents" or "the Cordis stents."

laration of Joseph A. Puma ("Puma Decl. "), ¶ 33). The metal stents are implanted in patients' arteries and serve as scaffolding to maintain open passageways in arteries that have been narrowed by disease.

Cordis has proferred some evidence indicating that the Cordis stents are not folded upon themselves, (Majercak Decl., ¶¶ 4-5), and that in using a Cordis balloon-expandable stent, physicians do not fold the stent upon itself (Puma Decl., ¶ 22). AGR admits that physicians do not fold the Cordis stents upon themselves during their use of the stents. However, the experts disagree as to whether Cordis' stents are "folded together compactly" so that one part is laid over another part. (*See, e.g.*, Deposition of Edward F. Leonard ("Leonard Depo."), 94:3-10; 95:12-15; 96:1-4; 103:7-25; 104; 105; 108:24-25; 109:1-10) (the Cordis stent is "folded compactly" and doubled over with one part lying over another part); Puma Decl. ¶¶ 20-22 ("[I]ts [Cordis'] stents are not 'folded,' that is, no part of the stent is laid over another part. The stent is never doubled upon itself"); Deposition of George P. Widas ("Widas Depo."), 92:21-24; 93:1-4 (the Cordis stent is not "bent upon itself")).

When Cordis' balloon-expandable stents are mounted on a balloon catheter, there is a portion of the **balloon** that extends beyond the stent, (Majercak Decl., ¶ 6; Puma Decl., ¶ 26), and when Cordis' balloon-expandable stents are mounted on a balloon catheter, there is a portion of the **catheter** that extends beyond the stent. (Majercak Decl., ¶ 7; Puma Decl., ¶¶ 28-29). Cordis' balloon-expandable stents are not positioned on the extreme or last portion lengthwise of the balloon, or on the extreme or last portion lengthwise of the catheter (Majercak Decl., ¶¶ 6-9), and physicians do not place Cordis' balloon-expandable stents on the extreme or last portion lengthwise of the balloon or of the catheter. (Puma Decl., ¶¶ 28-29). The experts disagree as to whether the Cordis stents are placed at or near an extremity of the catheter. (*See, e.g.*, Leonard Depo., 111: 11-25; 224:10-20) (Cordis' stent is

located near the end of the catheter); Puma Decl., ¶¶ 23-29) (Cordis' stent is not located at or near the end of the catheter; rather, it is located "at a distance"); *and see* Majercak Decl., ¶¶ 6-8 ("Cordis' stents and the balloon on which they are mounted are positioned so that the end of the catheter extends a distance beyond the stent and balloon.").

In the early 1990's, Dr. Palmaz's and Dr. Schatz's concept of a balloon-expandable stent was the subject of two large-scale clinical trials commissioned by J & J, which had taken a license in the Palmaz and Schatz Patents in 1986. Results from those clinical trials were published in the New England Journal of Medicine in August 1994. They showed that the Palmaz-Schatz stent was safe, effective and superior to angioplasty. Within weeks, the FDA approved the Palmaz-Schatz balloon-expandable stent for sale in the United States, and stenting quickly replaced angioplasty as the standard of care. Stents embodying the Palmaz and Schatz inventions have been used to treat millions of patients.

D. THE LICENSE AGREEMENT

In 1994, AGR began to negotiate with Cordis regarding granting Cordis world-wide exclusive rights to the inventions disclosed and claimed in the Rockey Patents. On January 24, 1995, Cordis and AGR entered into a Confidential Disclosure Agreement. On March 2, 1995, pursuant to the terms of the Confidential Disclosure Agreement, Cordis disclosed to AGR information regarding Cordis' projections of the commercial market for balloon-expandable stent products covered by the claims of the Rockey Patents. That information included Cordis' substantial sales and royalty forecasts based upon Cordis' expected commercialization of the technology disclosed and claimed in the Rockey Patents.

The License Agreement between Cordis and AGR was executed on May 15, 1995. The License Agreement granted Cordis an "exclusive world-wide license to manufacture, have manufactured, use and sell devices or products incorporating,

in whole or in part any and all of the inventions and improvements disclosed or claimed in the [Rockey] Patents." (License Agreement, § 2.1). Cordis would also "have the right to sublicense any Affiliate, or any third party who is not an Affiliate under the Patents to manufacture, use and sell devices or products incorporating in whole or in part any and all of the inventions and improvements disclosed or claimed in the Patents." (License Agreement, § 2.2). The "Patents" covered by the License Agreement are the three Rockey Patents and any and all continuations, continuations-in-part, divisions, reissues and foreign patent applications, and patents based on such Patents. (License Agreement, § 1.1.2). "Licensed Products" are defined as products which are "(i) sold, or (ii) used in a medical procedure, in a country where it is covered by any claim of the Patents." (License Agreement, § 1.1.2). "'Affiliate' means any entity which, directly or indirectly, controls or is controlled by, or is under common control with, Cordis." (License Agreement, § 1.1.5). J & J, the company that subsequently acquired Cordis, owns various organizations throughout the world, some of which are involved in the manufacture, use and sale of balloon-expandable stents. As defined by the License Agreement, J & J's Interventional Systems Company division constitutes an affiliate company of Cordis.

With regard to compensation, the License Agreement provided that Cordis would pay AGR advance or pre-paid royalties (the "Advance") of $2,000,000, comprising the following payments: (i) $500,000 upon execution of this agreement; (ii) $500,000 on July 1, 1995; and (iii) eight equal installments of $135,000 each, commencing on July 1, 1996, and every three months thereafter, up to the amount of $1,000,000. (License Agreement, § 3.1). The Agreement further provides that:

> [c]ommencing on the date ("Royalty Date") that Cordis, its Affiliates, and Sublicensees have cumulatively (i) sold, or (ii) used in a medical procedure, Li-

> censed Products (not including any Licensed Products (i) sold, or (ii) used in a medical procedure, before the Commercialization Date) having an aggregate Net Selling Price equal to $20,000,000 (such amount, the "Advance Sales"), Cordis shall pay to Licensor [AGR] a running royalty (the "Running Royalty") equal to 10% (the "Royalty Rate") of the Net Selling price of all Licensed Products (i) sold, or (ii) used in a medical procedure . . . . [N]o Running Royalties shall accrue until after the Royalty Date.

(License Agreement, § 3.2). "Net Selling Price" is defined as "the invoice price of the Licensed Products, less the following, according to the customary practice of Cordis, discounts allowed to distributors, discounts for clinical testing units (regardless of where the units are made or used), refunds, returns, the costs of replacement or credit freight, postage, shipping, insurance and other shipping charges, customs, duties and other governmental charges and import, use and sales tax)." (License Agreement, § 1.1.3). And, "commercialization date" is "the date on which the first commercial sale of any of the Licensed Products is made, after receipt of governmental approval to market the Licensed Products on an unrestricted basis." (License Agreement, § 1.1.4).

The royalties would be paid as follows:

> On the first day of the month after the expiration of three months after the Royalty Date, and each three months thereafter, Cordis shall determine the Net Selling Price of all Licensed Products (i) sold, or (ii) used in a medical procedure by Cordis, its Affiliates, and Sublicensees during the immediately preceding three month period and, within 15 days after the expiration of each such three month period, Cordis shall pay AGR the Running Royalty, if any. If no Running Royalties are due, Cordis shall send a written notice indicating the same to Licensor [AGR].

(License Agreement, § 4.2). Significantly, "[t]he obligation to pay a Running Royalty shall be imposed **only** once with respect to the same Licensed Products." (License Agreement, § 4.3) (emphasis added). Moreover, "[i]n the event that any claim of any of the Patents shall be declared invalid in any court of competent jurisdiction and in which no further appeal is available or is taken, no future royalty, Running Royalty or Advance payments shall be required in respect of such invalid claim." (License Agreement, § 4.4).

Among the warranties and representations made, AGR agreed that it knew of no entity or person who was infringing upon the rights of AGR in or to the Rockey Patents. (License Agreement, § 6.5). A merger or integration clause provides that the "License Agreement supersedes and replaces all previous agreements between the parties, and sets forth all of the agreements and understanding made between the parties hereto regarding the subject matter hereof." (License Agreement, § 14.1). The parties also agreed that the Agreement would be governed by Florida law. (License Agreement, § 14.3). Paragraph 14.9 of the License Agreement provides that "Cordis **may** attempt to obtain a term extension for the Patents if Cordis determines that the likely term extension will result in an additional amount of Running Royalties which exceeds the reasonable cost of obtaining such extension," and "Cordis shall provide Licensor [AGR] with information necessary to obtain any available term extension for the Patents from Patent and Trademark Office as a result of governmental regulatory approval." (emphasis added). The License Agreement was to finish at the end of the term for the last patent to expire of any of the Rockey Patents, (License Agreement, § 7. 1), and has never been terminated pursuant to the termination provisions of paragraph 7.2.

Pursuant to paragraph 3.1 of the License Agreement, Cordis paid AGR the sum of $2 million as an advance payment of pre-paid royalties. Approximately six months after execution of the License Agreement, on November 6, 1995,

Cordis agreed to be acquired by J & J, and the merger was completed in February 1996. Since then, Cordis has continued to sell balloon-expandable metal stents. Cordis has not paid the Running Royalty to AGR for the sale of any products, including its sales of Palmaz and Palmaz-Schatz stents. At all times since May 15, 1995, the date the License Agreement was executed, AGR has been the owner of the Rockey Patents. Neither AGR nor Cordis has filed an application to extend the term of any of the Rockey Patents under 35 U.S.C. § 156.

E. EXPERT TESTIMONY

The parties have identified experts, produced expert reports and conducted expert discovery. On June 9, 2003, AGR produced two liability expert reports from Dr. Edward F. Leonard ("Dr. Leonard") and George P. Widas ("Widas"). As set forth in the reports, the experts conducted an element-by-element analysis of claim 2 of the '1,653 Patent. In each instance where the experts addressed the respective claim elements, they did not limit their opinions to literal infringement.

Dr. Leonard has examined the Rockey Patents and various balloon-expandable stents sold by Cordis. Based upon his review of these materials, expertise in biomechanical engineering, and firsthand knowledge from working with balloon-expandable stents, Dr. Leonard has concluded that the Cordis stents infringe upon claim 2 of the '1,653 Patent. Referring to Cordis' stents, Dr. Leonard concludes:

> 30. Reviewing the Cordis documents, products and product inserts, it is clear that the Accused product is to be used for introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve or stent encircling the balloon on its end into a vessel at a point remote from the area to be treated. For instance, the coronary stent is inserted in the femoral artery which is remote from the coronary arteries, which is the area to be treated.

31. The device and its instructions further provide for manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated.

32. The instructions clearly provide for inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner where the sleeve surrounding the balloon is radially expanded towards the wall of the vessel. A review of the Accused Product clearly provides for radial expansion of the sleeve or stent through the inflation of the balloon.

33. Further, the Cordis Accused Products have a material in the sleeve which increases in rigidity after expansion of the balloon. That is, the stainless steel utilized in the stent or sleeve is internally strengthened by plastic deformation within each of its elements. It is also strengthened in its entirety by reorientation of its elements with respect to each other from an initial, predominantly axial orientation to a final, more circumferential position. This reorientation stiffens the stent and enables it to resist compressive stresses that tend to collapse it. Both changes result in an increase in rigidity over a period of time that includes the time during which the stent is freely expanding and an interval of time thereafter when the stent is accommodating to the blood vessel wall.

34. Subsequently, the balloon is removed and the catheter is removed from the vessel to allow the sleeve and stent to remain in place in the area to be treated.

35. It is my opinion to a reasonable degree of engineering certainty that based upon my review of the Accused Products and the method by which those

> products are specified for their use as described in the instructions provided, and with the devices furnished for their placement, that the accused device meets every limitation of claim 2 of the '1,653 Patent.

(Leonard Expert Report, at ¶¶ 30-35). Dr. Leonard's theory has three parts: (1) the geometric orientation of the tiny metal bars in Cordis' stents somehow changes after balloon expansion, in a way that increases rigidity of the stent, (2) the stainless steel in Cordis' stents undergoes plastic deformation for a brief period of time after the balloon is expanded, and (3) the stent increases in rigidity due to a supposed interaction between the stent and the wall of the artery during the 20-60 seconds that the balloon is maintained in an expanded condition before being deflated and withdrawn.

In his report, Mr. Widas also concludes that each of the elements of claim 2 of the '1,653 Patent can be found in the balloon-expandable stents sold by Cordis. Among the many opinions expressed by Mr. Widas, he concludes that the Cordis stents increase in rigidity after expansion of the balloon. (Widas Expert Report, ¶ 32).

Mr. Widas and Dr. Leonard hypothesize that after expansion of the balloon, the Cordis stents increase in rigidity to an infinitesimally small extent - which they have not even tried to measure. (Widas Expert Report, ¶¶ 32-33; Widas Depo., p. 156-57; Leonard Depo., 194:12-23). Mr. Widas' theory is that Cordis' stents undergo a phenomenon called "strain hardening" for an infinitesimally small period of time after the balloon stops expanding. According to Mr. Widas, this small amount of strain hardening results in a tiny increase in rigidity after expansion of the balloon.

Following AGR's production of its expert reports, Cordis was provided with the opportunity to depose Mr. Widas and Dr. Leonard. During those depositions, Cordis' counsel in-

quired regarding whether the experts had any opinion regarding the legal issue of the "doctrine of equivalents." Neither witness was prepared to offer opinions. However, throughout the course of the depositions, it was clear that both witnesses had included in their technical analyses and opinions, a recognition that the Cordis stents function in substantially the same way to achieve substantially the same result as the device set forth in the specification of the '1,653 Patent.

For example, Dr. Leonard testified to the following:

> Q. Do you have an opinion on whether or not the Cordis products infringe the claims if they do not have exactly what is called for in the claims?
>
> A. Yes, I do. I think that if they have substantially, what is called for in the claims, or - that is sufficient.
>
> Q. And how would you go about determining that?
>
> A. Functionally, to a large degree. That is to say that using the definition of a balloon, as an example I know what a balloon does and if something accomplished the same thing that a balloon did, and had a physical resemblance to a balloon, and could replace the balloon, but with no major difference in function, I would say that that was - that that was still covered by the original patent and it was infringing if you made something that did that.

(Leonard Depo., 68:14-25). In fact, Cordis was provided with additional notice that Dr. Leonard's opinions were not limited to literal infringement when Cordis' counsel asked the following questions:

> Q. You gave a certain understanding of the law about infringement. I want to know in that opinion, understanding was, that if it is not exactly what is in the claim there could still be an infringement. I want to know where that understanding of the law came from.

A. I drew it, I think in part from what I thought was logical and from statements of the kind that you see in the patent. For example, the invention is not restricted the Slavin [sic] limitation of each and every detail set forth. Devices may be provided which change, eliminate and add certain specific details without departing from the scope of the invention.

Q. As a legal matter, do you know what effect that sentence has, if any, on the rights of the patent?

A. No, I do not.

(Leonard Depo., 70:8-71:2).

The same is true with respect to the Widas deposition. During his deposition, Mr. Widas testified:

Q. In your work in patent cases have you ever heard of the doctrine of equivalents?

A. I have heard those words.

Q. Do you have any opinion on whether or not Cordis infringes claim 2 of the Rockey patent under the doctrine of equivalents?

A. You would have to explain it to me. I have heard the term, but I wouldn't know the significance of it in that context.

(Widas Depo., 56:8-19). Cordis' counsel did not explain the doctrine of equivalents, nor present an engineering question. Nevertheless, less than two pages later, the witness testified that his opinions regarding infringement were not based upon an "exact" reading of the claim:

Q. So if the Cordis device lacks one of the elements of the claim, then it does not infringe; is that correct?

A. Yes.

Q. Do you have any opinions on whether or not Cordis infringes the Rockey 2 patent if somebody determines that Cordis does not have exactly one of the elements?

A. Your word "exactly" is the only one that causes me hesitation.

Q. Okay.

A. I don't know and it is my understanding that it doesn't have to be exactly. That it has to be what it says.

(Widas Depo., 58:14; 59:6). Mr. Widas was offered as an expert on one element of claim 2. That is, Mr. Widas' opinion was limited to the material in the sleeve which increases in rigidity after expansion of the balloon due to plastic deformation (Widas Expert Report, ¶¶ 32-33). Counsel did not follow up with Mr. Widas regarding whether or not Widas had an opinion as to whether the sole element which was the subject of his report (*i.e.*, "providing in the sleeve a material which increases in rigidity after expansion of the balloon"), had to be found exactly in the accused device

Cordis has produced liability expert witness reports from Dr. Campbell Laird ("Dr. Laird") and interventional cardiologist Dr. Joseph A. Puma ("Dr. Puma"). Laird's report provides testimony with respect to the reverse doctrine of equivalents. (Laird Expert Report, p. 16-17). Thus, Cordis has presented expert testimony directly relating to whether the accused device functions in substantially the same way to achieve substantially the same result as the invention disclosed in the specification of the '1,653 Patent.

On July 9, 2002, AGR produced the rebuttal report of David P. Pope ("Dr. Pope"). The Pope Report addresses a number of issues raised by Dr. Laird, including Dr. Laird's testimony regarding the reverse doctrine of equivalents. Following the production of that report, on July 11, 2003, Cordis deposed Dr. Pope. During that deposition, Dr. Pope provided

the actual bases of his analysis regarding infringement in general, and specifically in connection with his opinion regarding infringement under the doctrine of equivalents. Dr. Pope testified regarding insubstantial differences between a stent made of metal and one made of polymer in terms of the way each increases in rigidity after expansion of the balloon. (Deposition of David P. Pope ("Pope Depo."), 78:16; 79:11). Dr. Pope opined that it is the expansion of the balloon that causes the stent to expand. Once the balloon stops expanding, so does the stent. (Pope Depo., 99:10-21). Since the stent only undergoes strain hardening when it is undergoing plastic deformation and being expanded, it cannot possibly undergo strain hardening after the balloon stops expanding. (Pope Depo., 124-125).

Dr. Pope expressly testified regarding the factual bases for his infringement analysis under the doctrine of equivalents:

> A. In the case of the metallic stent, the plastic deformation serves precisely the same function as the polymerization. That is to say, when the polymeric material is in its unmixed state, it has a resistance to change of essentially zero. That is to say, it's a liquid, so it deforms very easily. Then when it polymerizes and it becomes elastomeric, it becomes very resistant to shrinkage, and so you are comparing the resistance to shrinkage of the polymerized material to the liquid.
>
> In the case of the plastic material, you're comparing the resistance of expansion of the plastically deforming material to the contraction of the now elastically deforming material, and while that difference isn't the difference between a liquid and a solid, it is a change of resistance of some factors of hundred and therefore is a huge difference in the rigidity of the two.

(Pope Depo., 78:16; 79:11). Thus, AGR's experts have opined that a stent made of stainless steel, which is plastically deformed during expansion, functions in substantially the same way to achieve substantially the same result as a stent made by a polymer which undergoes polymerization and hardening upon expansion. In direct contrast to the opinions provided by AGR's experts on the doctrine of equivalents, Dr. Laird has provided testimony that the accused Cordis device does not function in substantially the same way to achieve substantially the same result.

On August 7, 2003, AGR filed its response to Cordis' Motion for Summary Judgment. Among the exhibits submitted in support of AGR's Response were declarations of AGR's three experts. These declarations provide additional analysis of infringement under the doctrine of equivalents.

AGR later submitted a Supplemental Expert Report of Dr. Leonard. The Supplemental Report further elaborates on Dr. Leonard's opinions on infringement under the doctrine of equivalents. Here, Dr. Leonard testifies that a polymer stent functions in substantially the same way to achieve substantially the same result as stent made of 316L stainless steel in that (1) "Both can be made so small so as to be able to be inserted into the body at a point remote from the area to be treated;" (2) both are "flexible and can be manipulated to the area to be treated," (3) "both can be expanded to varying sizes by a balloon mounted catheter;" (4) "both are made to increase in rigidity during and after expansion of the balloon;" (5) "both radically expand towards the wall of the vessel when the balloon is inflated;" (6) "both increase in rigidity while the balloon is maintained in an expanded condition;" and (7) "both remain in place in the area to be treated after the balloon and catheter are removed from the vessel." (Leonard Supplemental Report, ¶¶ 7-12).

Additionally, in his Supplemental Report, Dr. Leonard responded to opinions of Cordis' experts, Drs. Laird and Puma,

that Dr. Rockey's Patent Application Serial No. 912,010 does not disclose the use of a material which increases in rigidity after expansion of the balloon. Dr. Leonard reviewed Dr. Rockey's applications concludes that both the '010 Application and the '989 Application disclosed to one skilled in the art all of the limitations found in claim 2 of the '1,653 Patent. (Leonard Supplemental Report, ¶ 17).

AGR has also produced the expert report of attorney William H. Murray. In his report, Mr. Murray relies upon Dr. Leonard's Supplemental Report. AGR's stated purpose for Mr. Murray's testimony is to explain to the jury that, based upon his review of the Patent file history, as well as his reliance upon a person skilled in the art, the Rockey Patents are entitled to an effective filing date of June 1978. AGR intends to have Mr. Murray testify regarding the effect of the patent application process which resulted in the '1,653 Patent.

F. QUALIFICATIONS OF THE EXPERTS

Dr. Leonard is a chemical and biomedical engineer. Dr. Leonard obtained his undergraduate degree in 1953 from the Massachusetts Institute of Technology, and later obtained his masters and doctorate in chemical engineering from the University of Pennsylvania. Since 1968, Dr. Leonard has been a professor at Columbia University, where he currently teaches chemical and biomedical engineering. Dr. Leonard has been involved in biomechanical engineering for approximately 56 years. Dr. Leonard holds a patent for a catheter device. He has also conducted research with stents, including their placement and analysis after removal. For approximately eight years, part of Dr. Leonard's work included consulting for Interventional Technologies, now part of Boston Scientific, Inc. With regard to balloon-expandable stents, Dr. Leonard's experience includes using balloon-expandable stents in research; helping design stents for Interventional Technologies; researching the interaction between stents and vessel walls; providing consulting services on a variety of stent issues involving fluid

mechanics, tissue reactions and controlled release theory; calculating and examining the ability of stents to withstand compressive stresses and having many discussions with interventional cardiologists regarding stenting procedures.

Mr. Widas is a professional engineer with over 30 years of experience, including advanced engineering studies in biomechanics. He has received professional training in the areas of physics, mechanics, vectors, deformable bodies and material behavior. He is a consultant in the application of the physical sciences and principles of safety engineering to event analysis and reconstruction.

Dr. Pope and Dr. Laird are materials scientists, or metallurgists. Dr. Laird has a doctorate in physics, chemistry and mathematics, and has been practicing in the field of materials science and engineering for 44 years. He is a professor in this subject at the University of Pennsylvania. Dr. Pope is also a professor of materials science and engineering at the University of Pennsylvania, and has a doctorate in materials science. Both Drs. Pope and Laird are experts in the properties of various materials, including stainless steel.

Dr. Puma, an interventional cardiologist, has been using stents for over a decade and performs 200-400 interventional procedures a year. Dr. Puma participated in one of two major clinical trials that showed that the Palmaz-Schatz stent significantly reduced the rate of restenosis[4] as compared to balloon angioplasty. He is an Associate Consulting Professor of Medicine (Cardiology) at Duke University Medical Center. Dr. Puma is familiar with the treatment of ischemic heart disease from surgical coronary artery bypass grafting to balloon angioplasty, to the current treatment, stenting. He is also familiar with how stents became the standard of care for treat-

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[4] Restenosis is a narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or a stent procedure, has already taken place.

ing ischemic heart disease and how interventional cardiologists use Cordis stents.

Dr. Puma is familiar with stent designs, having used stents for over a decade. He has reviewed marketing literature describing stents and has examined stents in practice. Dr. Puma is skilled in using a catheter and balloon and removing them from a vessel. Dr. Puma uses balloons mounted on catheters and removes them from the vessel in his stenting procedures. He has expertise in what happens to stainless steel upon expansion.

William H. Murray is a registered patent attorney in the law firm of Duane Morris, LLP, in Philadelphia, with 29 years of experience in the field of intellectual property. He has prepared or supervised the preparation of hundreds of United States patent applications. He has testified as a patent expert in three judicial proceedings.

Cordis does not intend to offer any expert or opinion testimony by Dr. Palmaz at trial. If permitted to testify, Dr. Palmaz would testify as a fact witness. Dr. Palmaz would testify about his inventions disclosed in U.S. Patent Nos. 4,833,665 and 4,739,762. He would discuss his initial conception of the idea, his animal experiments and implants starting in 1984, and ultimately his collaboration with J & J to commercialize the invention.

II. PROCEDURAL BACKGROUND

AGR brought this action against Cordis in state court on July 1, 2002. Count I is for breach of contract based on Cordis' failure to pay the Running Royalty under the License Agreement, despite AGR's written request for payment. AGR alleges that Cordis was obligated under the License Agreement to extend the term of the Rockey Patents. AGR claims that Cordis' failure to pay the Running Royalty, and its failure to extend the life of the Rockey Patents, constitute material breaches of the License Agreement.

In Count II, for breach of the duty to exploit, AGR claims that the exclusive licensing provision of the License Agreement subjects Cordis to an express duty to commercially exploit the technology covered by the Rockey Patents. In addition, the exclusive licensing provision allegedly subjects Cordis to an implied duty to use its best efforts to commercially exploit the inventions in the Rockey Patents.

Count III is for breach of the duty of good faith and fair dealing in connection with the License Agreement. AGR relies on the language in the Agreement that Cordis "may" attempt to obtain a term extension for the Rockey Patents. Such an extension would have resulted in a longer period of time during which Cordis would have been obligated to continue to pay the Running Royalty. AGR alleges that Cordis did not seek to extend the life of the Rockey Patents in an effort to avoid its continuing obligation to pay AGR the Running Royalty based on the sale of Licensed Products by Cordis and its affiliates. Cordis' failure to extend the life of the Rockey Patents, it is alleged, constitutes a breach not only of the License Agreement, but also of Cordis' duty of good faith and fair dealing. AGR seeks declaratory relief and damages for lost revenues, lost past royalties and lost future royalties on all counts.

Cordis maintains that Count I fails because Cordis' stents are not the medical sleeves that Dr. Rockey invented and that AGR licensed to Cordis. Cordis claims that its stents are an entirely different kind of device; they are based on inventions by Dr. Palmaz and Dr. Schatz, which were independently licensed to Cordis. Cordis raises the following affirmative defenses in its Answer to the Complaint: (1) the Complaint fails to state a claim upon which relief may be granted; (2) AGR's claims are barred under the doctrines of laches, waiver and estoppel; (3) AGR's claims are barred in whole or in part under the statute of limitations; (4) neither Cordis nor its "affiliates" (as that term is used in the License Agreement) makes, uses, sells or offers for sale, or has ever made, used, sold or

offered for sale, any product that is covered by the Rockey Patents, (5) if any claim of the Rockey Patents is construed so as to cover any of the Cordis balloon-expandable stent products, then any such claim is invalid under 35 U.S.C. § 102, 103 and/or 112, and (6) if any of Cordis' balloon-expandable stent products literally meet the limitations of any of the claims of the Rockey Patents, then any such products do not infringe the Rockey Patents under the reverse doctrine of equivalents. Cordis admits to the following: (1) Cordis has not paid the Running Royalty to AGR (because Cordis does not owe any Running Royalty to AGR); (2) in or about early 1996, Cordis became a J & J company; (3) Cordis sells a product called the Palmaz Balloon-Expandable Stent; (4) Cordis has not extended the life of any of the Rockey Patents; (5) Cordis' obligation to pay a Running Royalty would not begin until after Cordis had sold in excess of $20,000,000 worth of products covered by the Rocket Patents; and (6) the PTO issued the Rockey Patents referenced in the Complaint.

Cordis filed a Notice of Removal pursuant to 28 U.S.C. § § 1441 and 1446, asserting that this Court had jurisdiction under 28 U.S.C. § 1338 because Count I necessarily depends on the resolution of a substantial question of federal patent law. In its Motion to Remand, AGR argued that Counts II and III presented alternative legal theories for the breach of contract claim under which resolution of a patent law issue is not essential. Cordis responded that in order to prevail on its claim for royalties under Count I, AGR had to prove that Cordis' stents are Licensed Products, those being stents covered by at least one claim of the Rockey Patents and, accordingly, that AGR had to prove the stents would infringe on one of the Rockey Patents but for Cordis' license to use those Patents.

AGR's Motion to Remand was denied by Order dated November 12, 2002 (D.E. 26). The Court[5] found that all of AGR's claims arise out of or relate to the parties' License Agreement. Noting that the "Court's task here is to determine whether any one of the Rockey, Inc,'s claims depends on the resolution of a substantial issue of federal patent law," the Order further stated:

> Even though Rockey, Inc. denominates Count I as a simple state law breach of License Agreement claim, it seems obvious that **for Rockey, Inc. to prevail on that claim, Rockey, Inc. will have to prove that the stents sold by Cordis are covered by Dr. Rockey's patents. Stated in patent terminology, Rockey, Inc. must prove that the stents resulted from Cordis practicing Dr. Rockey's patent, as Cordis was entitled to do under the License Agreement.** Rockey, Inc. would have to read the patent onto the stents, which Rockey, Inc. contends are Licensed Products, in order to prove its claim for royalties .... The Court concludes that because one of Rockey, Inc.'s three claims, Count I, requires the resolution of a substantial question of federal patent law, the Court has 'arising under' jurisdiction pursuant to § 1338(a).

Id. (emphasis added). With respect to AGR's argument that Counts II and III did not involve a federal patent law issue, and were alternative to Count I, the Court rejected AGR's contention, finding Counts II and III to be not alternative theories, but rather additional claims, independent of AGR's breach of contract claim for royalties resulting from Cordis' sale of Licensed Products.

The Order suggested that interlocutory review by the United States Court of Appeals for the Federal Circuit under

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[5] That Order was entered by the Honorable Paul C. Huck, United States District Court Judge for the Southern District of Florida, before the case was transferred to the undersigned.

28 U.S.C. §§ 1292(b) and (c) may be appropriate because the Order "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation" in a patent infringement case over which the Federal Circuit would have exclusive jurisdiction of appeals under 28 U.S.C. § 1295. Accordingly, AGR filed a petition for permission to appeal the November 12, 2002 Order with the Federal Circuit. The Federal Circuit exercised its discretion in denying AGR permission to appeal, noting that "[i]t appears that the parties agreed that the first count, concerning breach of the license agreement, arose under the patent laws, such that a federal district court would have jurisdiction over that count." (D.E. 36).

The parties have filed the various motions *in limine* listed above. Cordis has also filed a motion for summary judgment, and a separate motion for claim construction of the terms of the '1,653 Patent in lieu of a summary judgment favorable to Cordis.

III. LEGAL DISCUSSION

A. AGR'S MOTIONS *IN LIMINE*

1. AGR's Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents

AGR seeks to preclude the introduction at trial of any evidence regarding the validity of the three Rockey Patents covered by the License Agreement. AGR argues that, based on the License Agreement, the validity of the claims of the '1,653 Patent, or of any of the other two Rockey Patents, is not relevant to any issue before the jury. AGR contends that the validity of the Rockey Patents has no effect upon Cordis' obligations to pay **past** royalties under the License Agreement. In this regard, paragraph 4.4 of the License Agreement provides:

> In the event that any claim of the Patents shall be **declared** invalid in any court of competent jurisdiction and in which no further appeal is available or is taken, no **future** royalty, Running Royalty or Advance payment shall be required in respect of such invalid claim.

(emphasis added). AGR also argues that "there is no cause of action which could in any way support a **declaration** of invalidity of any claim of the Rockey Patents." (Motion, p. 4) (emphasis added).

Cordis' position is that claim 2 of the Rockey '1,653 Patent does not cover Cordis' stents, and that if the claim were construed so broadly so as to reach Cordis' stents, then the claim would be invalid under 35 U.S.C. §§ 102 (a) and 102(g), because Dr. Palmaz invented the subject matter first. Cordis further argues that invalidity would negate AGR's claim for Running Royalties because the License Agreement provides that Cordis owes Running Royalties only on "Licensed Products," which are defined in the Agreement as products that are "covered by" any claim of the Rockey Patents. According to Cordis, this language requires a licensor to pay royalties only on products that would infringe the licensed Patents under federal patent law.

The plain language of paragraph 4.4 of the License Agreement does not limit the effect of a finding of invalidity to **future** royalties. Rather, the Agreement limits liability for future royalties **as well as** Running Royalties and the Advance Payment. This language makes clear that if any claim of the Rockey Patents is found invalid, then Cordis is not required to pay "future royalties," or "Running Royalties," or "Advance Payment." Accordingly, a finding that claim 2 of the '1,653 Patent is invalid would provide a complete defense to AGR's claim for Running Royalty payments.

The invalidity of claim 2 is not just a defense under the Agreement, and therefore a relevant inquiry, it is also a de-

fense as a matter of substantive patent law. Cordis has specifically pled invalidity of the Rockey Patents under 35 U.S.C. §§ 102, 103, and/or 112 as an affirmative defense. Accordingly, experts offered by both parties have opined on the validity of the Rockey Patents. Under 35 U.S.C. § 282, invalidity may be raised as an affirmative defense in any "action involving ... infringement." *See also Stairmaster Sports/Medical Prod., Inc. v. Groupe Procycle, Inc.*, 182 F.R.D. 117, 118-19 (D. Del. 1998); *Cornwall v. U.S. Constr. Mfg., Inc., et al.*, 800 F.2d 250, 252-53 (Fed. Cir. 1986) (citing 35 U.S.C. § 282). Moreover, Section 282 provides a clear statutory authority for a **declaration** of invalidity. *Constant v. Advances Micro-Devices, Inc.*, 848 F.2d 1560, 1563-64 (Fed. Cir. 1988) ("[35 U.S.C. § 282] permits the federal courts to adjudicate the validity of patents when invalidity is raised as an affirmative defense in infringement suits.").

And it is the law of this case that AGR's claim for Running Royalties is a claim involving infringement. The Order denying AGR's Motion to Remand states that to prevail on its claim for Running Royalties, AGR must show that "the stents sold by Cordis would have infringed" the Rockey Patents but for the License Agreement. *See also Interspiro USA, Inc. v. Figgie Int'l, Inc.*, 18 F.3d 927, 930 (Fed. Cir. 1994) (finding that when an agreement requires a party to pay royalties on sales "covered by" a patent, the issue of whether the party must pay a royalty "turns on whether the [accused product] infringes [that] patent"). Thus, as this is a case "involving infringement," invalidity of the '1,653 Patent is available as a defense.

AGR misinterprets the November 12, 2002 Order in suggesting that it establishes only that federal law provides the basis for jurisdiction but need not be applied to Count 1, and rather that state law controls the breach of contract count. This is not the clear holding. The ruling was based on the application of **federal** law to the issue of patent infringement that is necessary to the resolution of Count I, and to which

state law cannot provide the grounds for decision. *See, e.g., 3D Sys., Inc. v. Aarotech Laboratories, Inc.*, 160 F. 3d 1373, 1379 (Fed. Cir. 1998) (holding that a determination on patent infringement was an issue governed solely by federal law, not state contract law because "[d]efining the contours of the tort of [patent] infringement, which exists solely by virtue of federal statute, entails the construction of the federal statute [and federal common law] and not a state's common or statutory law").[6]

The Court is bound by the law-of-the-case doctrine. The Supreme Court has described the law-of-the-case doctrine as follows:

> A court has the power to revisit prior decisions of its own court or of a coordinate court in any circumstances, although as a rule courts should be loath to do so in the absence of extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'

Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 817 (1988). The Eleventh Circuit has clarified: "Courts must rarely invoke the 'clear error' exception, less the exception swallow the rule." *Jenkins Brick Co. v. Bremer*, 321 F.3d 1366, 1370 (11th Cir. 2003); *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000). AGR does not argue, nor does the record reflect, that the November 12, 2002 Order was erroneous, let alone "clearly erroneous." Because the jury will be asked to consider patent infringement on

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[6] Decisions by the U.S. Court of Appeals for the Federal Circuit provide controlling authority on the aspects of this case that are unique to patent law. *Lummus Indus. v. D.M & E. Corp.*, 862 F.2d 267, 270 (Fed. Cir. 1988). Decisions by the Eleventh Circuit govern issues that are not unique to patent law, *see id.*, and Florida provides the applicable state law because the parties chose Florida law to govern their Agreement. (License Agreement, § 14.3).

Count 1, and invalidity of the '1,653 Patent is a defense that is available to Cordis on this claim, evidence regarding the validity of the Rockey Patents[7] is relevant and admissible.

2. AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony, and Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985 for Claim 2 of the '1,653 Patent

AGR moves to preclude the introduction at trial of any evidence concerning Dr. Palmaz's alleged conception of the Palmaz stent prior to 1980, even though his first patent application date concerning this device is November 7, 1985. There is not only conflicting evidence as to Dr. Palmaz's conception date,[8] but there is also conflicting expert evidence as to what priority date should apply to claim 2 of the Rockey '1,653 Patent. The application that resulted in the '1,653 Patent was filed on February 19, 1985. AGR's theory is that a 1978 priority date applies to claim 2 of the '1,653 Patent because Dr. Rockey filed a different patent application on June 2, 1978, and the '010 Application disclosed the same invention described in claim 2. Cordis argues that AGR is not entitled to the earlier filing date because AGR cannot show that the '010 Application filed in 1978 disclosed each and every limitation of claim 2. However, Cordis admits that whether or not AGR is entitled to only a 1985 priority date based on a limitation-by-limitation analysis is a "disputed issue" for the jury.

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[7] Because AGR seeks application of the earlier filing date of one of the other Rockey Patents to the '1,653 Patent based on the disclosure of the same invention, evidence regarding validity of **all three Rockey Patents** is relevant and may be introduced at trial.

[8] AGR concedes that there is conflicting evidence on this issue in its Reply brief, asserting that "[a]lthough **unclear**, it appears that Dr. Palmaz allegedly conceived of his invention **sometime between 1978 and 1984.**" (Reply, p. 1) (emphasis added).

Because invalidity of the Rockey '1,653 Patent is an affirmative defense, and because the determination of who is the prior inventor of the technology is relevant to the issue of validity, it will be the jury's function to weigh the conflicting evidence to determine what priority dates should be applied to the Palmaz invention and the Rockey invention. The cross-motions are therefore denied.

3. AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph Puma

AGR moves *in limine* to preclude the expert opinion testimony of Drs. Laird and Puma at trial. AGR maintains that these expert witnesses offered by Cordis lack experience in the design, study, evaluation and testing of medical devices, including the stent technology at issue.

To the contrary, the record shows that Drs. Laird and Puma are sufficiently skilled in the relevant art so that their testimony may assist the jury in understanding the evidence relating to the devices developed by Drs. Rockey and Palmaz. As a materials scientist, Dr. Laird is an expert with regard to the properties of various materials, including stainless steel, which is the material contained in the Cordis stents. (Laird Expert Report, p. 1-2). Indeed, he states that the focus of his "research and professional activities has been fracture and deformation, especially fatigue and cyclic deformation, and the interrelationship of these phenomena with static fracture and deformation." (Laird Expert Report, p. 2).

Dr. Puma has been using balloon-expandable stents such as the Palmaz-Schatz stent for almost a decade. He conducts at least 200 to 400 procedures involving stents every year. (Puma Expert Report, p. 1). Dr. Puma has even participated in a major clinical trial conducted in the United States to assess the effectiveness of the stenting procedure using the Palmaz-Schatz stent in comparison with another treatment. (Puma Expert Report, p. 9).

Dr. Laird will, therefore, be permitted to testify at trial regarding general principles of material science. Dr. Puma will be permitted to testify regarding stent technology and design, including that of the Cordis stents, and stenting procedures used to treat heart disease. Additionally, both Drs. Laird and Puma, based on their particular experience in the relevant art, will be permitted to offer opinions on the validity of the Rockey '1,653 Patent, and on infringement of the terms of claim 2 of the '1,653 Patent, as those terms are construed in this Order.

4. AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony

The parties agree that fact witnesses should not be permitted to testify regarding undisclosed expert or opinion testimony. Accordingly, the parties shall not offer any undisclosed expert or opinion testimony through their fact witnesses, or elicit such testimony from the opposing party's fact witnesses.

5. AGR's Motion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection

AGR seeks to exclude evidence concerning the development by J & J of the Palmaz balloon-expandable stent subsequently sold by Cordis, and the award of United States patents to Dr. Palmaz covering this accused device. Contrary to AGR's assertions, such evidence is relevant to several issues in this case, including but not limited to, the validity of the Rockey '1,653 Patent and the "equivalence" of the Rockey sleeve and the Palmaz stent under the doctrine of equivalents. Courts have found that patentability of an accused product is **relevant** in cases involving a determination of infringement under the doctrine of equivalents. *See, e.g., Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*, 344 F.3d 1226, 1233 (Fed. Cir. 2003) ("**this fact [a patent covering the accused product] may be weighed by the district court**, particularly

if there is an issue of 'insubstantial' change with respect to equivalency") (emphasis added), *National Presto Indus., Inc. v. West Bend Co., Inc.*, 76 F. 3d 1185, 1191-92 (Fed. Cir. 1996) ("Whether a modified device is within the scope of the prior patent, literally or by equivalency, depends on the particular facts. **The fact of separate patentability is relevant, and is entitled to due weight.**") (citing *Atlas Powder Co. v. E.L. du Pont de Nemours & Co.*, 750 F.2d 1569, 1580-81 (Fed. Cir. 1984)) (emphasis added); *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 (Fed. Cir. 1993); *Magnesystems, Inc. v. Nikken, Inc.*, 933 F. Supp. 944, 952 (C.D. Cal. 1996). Nevertheless, "[t]he grant of a separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent." *National Presto*, 76 F.3d at 1191-92 (citation omitted). Thus, the separate patents issued to Dr. Palmaz and other inventors are relevant, although not dispositive of the determination of infringement.[9]

B. CORDIS' MOTIONS *IN LIMINE*

1. Cordis' Motion *in Limine* to Exclude Parol Evidence

Cordis seeks to preclude AGR from introducing parol evidence of the parties' intent when they entered into the License Agreement. For example,

> Cordis seeks to preclude admissions made by Cordis representatives to Gina Rockey that AGR's patents 'were very broad,' that the License Agreement would cover both metal and polymer stents, and that Cordis

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[9] Moreover, it is not readily apparent that admission of evidence on the development of and the patentability of the Palmaz stents and other stents sold by Cordis would create unfair prejudice to AGR or jury confusion.

> projected AGR's royalties to be in excess of $100,000,000 under the License Agreement.

(AGR's Response, p. 6). It is AGR's position that the License Agreement is clear and unambiguous in that it provides that Cordis is liable to AGR for royalty payments based on the sale of any stents that incorporate "in whole or in part" any of the improvements set forth in the Rockey Patents. However, AGR maintains that if the License Agreement found to be ambiguous, parol evidence is necessary to clarify an ambiguity. Moreover, and in the alternative, AGR relies on the fraudulent inducement exception to the parol evidence rule under Florida law, which permits parol evidence of a contemporaneous oral agreement to "vary, change, or reform" a written agreement, but not directly contract it. (AGR's Response, p. 5-6 (citing *Ungerleider v. Gordon*, 214 F.3d 1279, 1282 (11th Cir. 2000))); *see Mallard v. Ewing*, 121 Fla. 654, 664 (1935).

In response to AGR's first argument, Cordis maintains that evidence regarding the parties' intent and/or any pre-contractual oral agreements is irrelevant and inadmissible because there is no ambiguity in the License Agreement concerning Cordis' obligations to pay royalties. The License Agreement requires Cordis to pay royalties **only** on "Licensed Products," and it explicitly defines "Licensed Products" as products that are "covered by any claim of the [Rockey] Patents." This language requires Cordis to pay royalties **only** on products that would "infringe the [licensed] patent[s]" under federal patent law. Indeed, this is precisely the interpretation of the License Agreement adopted in the November 12, 2002 Order.

Two provisions of the License Agreement address Cordis' obligation to pay royalties: paragraphs 1.1.2 and 3.2. Paragraph 3.2 states that "Cordis shall pay to Licensor a running royalty" on sales of "all Licensed Products." "Licensed Products," in turn, are defined in paragraph 1.1.2 as products that

are "covered by any claim of the Rockey Patents." The License Agreement obligates Cordis to pay royalties only on products that infringe a claim of the Rockey Patents.

AGR cites to paragraph 2.1 of the License Agreement, which grants Cordis "an exclusive, world-wide license to manufacture, have manufactured, use and sell devices or products incorporating **in whole or in part** any and all of the inventions and improvements disclosed or claimed in the Patents." (emphasis added). AGR presumably relies on this provision to support its claim that Cordis agreed to pay royalties on products that use only **a part** of the invention disclosed or claimed in the Rockey Patents. This argument is unavailing. Paragraph 2.1 has no bearing on Cordis' obligation to pay royalties; rather, it defines the scope of the license rights granted to Cordis under the Agreement. Therefore, there is no conflict between paragraph 2.1 and paragraphs 1.1.2 and 3.2, and no ambiguity in the License Agreement is created by a comparison of these provisions.

AGR's reliance on *Gjerlov v. Schuyler Laboratories, Inc.*, 131 F.3d 1016 (Fed. Cir. 1997) is misplaced. In that case, the Federal Circuit applied Iowa law to a question of interpretation of a settlement agreement reached in a patent infringement action. The Court held that the issue of contract interpretation was not governed by federal patent law, but by state contract law, in an action alleging breach of the contract, and the Court considered parol evidence to resolve an ambiguity in the contract. *Id.* at 1020-22. The ambiguous terms of the contract were terms that were also used in the claims of the patent, which is not the case here.

This Order does not depart from the holding in *Gjerlov*. Applying Florida law to the issue of contract interpretation, there is no ambiguity in the License Agreement that would warrant consideration of parol evidence. None of the disputed terms contained in claim 2 of the '1,653 Patent are contained in the License Agreement; therefore, parol evidence relating

to the parties' intent in negotiating the terms of the License Agreement would not be helpful in determining patent infringement. Furthermore, although Florida law governs contract interpretation, it does not apply to the determination of patent infringement. The question of whether any of Cordis' products are "covered by any claim of the [Rockey] Patents" is solely a question of federal patent law.

The fraudulent inducement exception to the parol evidence rule is also inapplicable here because this exception allows a fact-finder to consider parol evidence "where the legal existence or binding force of the instrument is in question." *Tinker v. De Maria Porshe Audi, Inc.*, 459 So.2d 487, 491 (Fla. 3d DCA 1984) (citing *Bleemer v. Keenan Motors, Inc.*, 367 So.2d 1036, 1037 (Fla. 3d DCA 1979)). A finding of fraud based on such extrinsic evidence renders an accompanying breach of contract claim moot. *See Lou Bachrodt Chevrolet, Inc. v. Savage*, 570 So.2d 306, 308 (Fla. 4th DCA 1990). AGR did not plead fraudulent inducement. It has never challenged the "legal existence or binding force" of the License Agreement. To the contrary, in its breach of contract claim AGR seeks to enforce the terms of the License Agreement that obligate Cordis to pay royalties.

AGR relies on *Wise v. Quina*, 174 So.2d 590, 596 (Fla. 1st DCA 1965), to argue that "parol evidence is admissible to establish a contemporaneous oral agreement which induced the execution of a written contract, though it may vary, change or reform the instrument." (quoting *Mallard*, 121 Fla. at 664). *Wise* is inapposite. In *Wise*, the plaintiffs wished to enforce an oral representation made by the defendants at the time they purchased a real estate subdivision, but that oral representation did not contradict any provision of the purchase agreement. It is also unclear from *Wise* whether the sale agreement contained a merger clause, as does the License Agreement in this case.

Moreover, as the party wishing to invoke the fraudulent inducement exception, AGR "carries a heavy burden of proof." *Ungerleider*, 214 F.3d at 1282. It would need to establish a purported oral agreement "by evidence that is clear, precise, and indubitable." *Johnson Enter of Jacksonville, Inc. v. FPL Group, Inc.*, 162 F.3d 1290, 1310 (11th Cir. 1998) (quoting *Mallard*, 121 Fla. at 678) (other citations omitted). Where "the existence of the [supposed] contemporaneous oral agreement rests solely on a credibility choice between two witnesses," parol evidence, as a matter of law, is not "clear, precise, and indubitable." *Id.* (citing *Chase Manhattan Bank v. Rood*, 698 F.2d 435, 438 n. 4 (11th Cir. 1983); *Mallard*, 121 Fla. at 678)). Such is the case here. AGR's entire proof of a contemporaneous oral agreement rests on the contradicted testimony of AGR's principal, Gina Rockey Collias. The existence of any supposed extra-contractual "agreement" between the parties is disputed, to say the least, and therefore inadmissible under the inducement exception. *See Johnson*, 162 F.3d at 1310.

Cordis' obligations to pay royalties will be determined based on the language of the License Agreement and proper construction of the Rockey Patents under federal patent law. Parol evidence of any other agreement or understanding between the parties is not be relevant to contract interpretation or claim construction,[10] and is therefore excluded.

2. Cordis' Motion *in Limine* to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on Products that Practice the Rockey Patents "In Whole Or In Part"

In opposing Cordis' Motion, AGR argues that the License Agreement "expressly provides that Cordis is liable to AGR

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[10] As discussed *infra* in the section of the Order addressing claim construction and application under federal patent law, claim construction is a matter of law that is "exclusively within the province of the court." *See, e.g, Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

for the sale of any stents that incorporate '**in whole or in part**' any of the improvements set forth in the Rockey Patents." (AGR's Response, at p. 5)(emphasis added). Similarly, in opposing Cordis' Motion for Summary Judgment, AGR argues that Cordis is obligated to pay royalties on the sale of any product "that utilized '**in whole or in part**', the inventions **disclosed or claimed** in the Rockey Patents." AGR Response to Cordis' Motion for Summary Judgment, at 1-2 (underlining in original; bold emphasis added). Cordis seeks to preclude AGR from offering this reading of the License Agreement in its arguments to the jury.

Cordis' Motion is well taken because, as already noted, paragraph 2.1 of the License Agreement, containing the "in whole or in part" language, does not relate to Cordis' obligation to pay royalties. Moreover, under applicable federal patent law, there cannot be a finding infringement if **any** claim limitation is **literally or equivalently** absent in the accused device. *See, e.g., Techsearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002) ("To establish literal infringement [and infringement under the doctrine of equivalents], **all of** the elements of the claim, as correctly construed, must be [literally or equivalently] present in the accused system") (emphasis added); *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995) ("every limitation set forth in a claim must be found in an accused product"). Accordingly, AGR is precluded from arguing to the jury, or presenting any evidence, regarding Cordis' supposed obligation to pay royalties on products that practice the Rockey Patents "in whole or in part."

3. Cordis' Motion *in Limine* to Exclude or Limit the Testimony of AGR's Patent Law Expert

AGR has identified patent attorney, William H. Murray, Esq. ("Murray"), as one of its expert witnesses. Murray is not a scientist, engineer or physician, and therefore, is not skilled in that relevant art. Murray is a registered patent attorney with

29 years of experience. In this case, Murray bases his opinions on the opinions of Dr. Leonard, including Dr. Leonard's opinions on whether the '010 Application disclosed every limitation of claim 2 of the '1,653 Patent.

Cordis seeks to exclude Murray's testimony, arguing that it will add nothing new. Cordis concedes that patent law experts may testify as to the general procedures involved in the patent application process, but, because they are not themselves experts in the relevant art, they may not testify on whether the '010 Application discloses every limitation of claim 2 of the '1,653 Patent. Cordis further argues that Murray may not render testify as to the legal requirements for the '1,653 Patent claims to enjoy the benefit of the earlier filing date of the '010 Application, because it is the function of the Court, and not patent law experts, to instruct the jury on applicable law.

AGR maintains that Murray's testimony will be presented to assist the jury in connection with their determination regarding the effective filing date of the Rockey Patents, which, as previously mentioned, is relevant to Cordis' invalidity defense:

> The purpose of Mr. Murray's testimony is to explain to the jury that, based upon his review of the patent's file history, as well as his reliance upon a person skilled in the art, that the Rockey Patents are entitled to an effective filing date of June 1978. Mr. Murray will testify regarding the effect of the patent application process which resulted in the '1,653 Patent. The testimony is relevant to the jury's determination as to whether the work of Palmaz and others after June 1977 constitutes prior art.
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> * * *

> Mr. Murray will testify that ... there would have been no reason for Dr. Rockey to have filed a continuation-in-part on February 19, 1985.
>
> * * *
>
> Put another way, Mr. Murray will testify that based upon his reliance upon the expert, nothing in those applications constitutes new matter sufficient to warrant the filing of a continuation-in-part application [in either 1980 or 1985].

(Response, p. 4.). Furthermore, in his expert report, Murray states that he expects to testify about (1) the issue of PTO procedures, and in particular whether or not the invention disclosed in claim 2 of '1,653 Patent is entitled to the benefit of the June 2, 1978 filing date of '010 Application in accordance with 35 U.S.C. §120,(2) in general, the requirements for entitlement to the benefit of an earlier-filed patent application; and (3) the conclusions reached in the expert reports of Drs. Puma and Laird that claim 2 of the '1,653 Patent is not entitled to the benefit of the 1980 filing date of the '989 Application or the 1978 filing date of the '010 Application.

It does appear that AGR intends to offer Murray exclusively as an expert in patent law. The information he expects to provide could be helpful to a jury to clarify the language of the claims as interpreted by the scientific experts. In *Lemelson v. General Mills, Inc.*, 1987 WL 26134, *1 (N.D. Ill. 1987), for example, the Court denied a motion *in limine* to exclude the testimony of plaintiff's patent attorney expert on the issues of validity of a claim of the patent at issue and any infringement by defendant of that claim, where his proffered testimony was based both on his expertise in the field of patent law and the technical foundation established at trial by experts in the relevant art. The Court noted that the attorney's "opinions on these issues will merely 'take the further step of suggesting the inference which should be drawn from applying the specialized knowledge [in patent law] to the facts [of

toy design art]. "' *Id.* (citing Fed. R. Evid. 702, Notes of Advisory Committee on Proposed Rules). In *Lemelson*, the attorney's testimony was offered to show "the relationship of the technical information to the issuance of a valid patent and to determining infringement of such a patent." *Id.* The Court found the testimony admissible under Rule 702 of the Federal Rules of Evidence[11] because "the untrained layman is not qualified to assess this relationship intelligently and to the best possible degree without the aid of expert testimony." *Id.* The Court also found that the attorney's testimony would not duplicate the other experts' testimony because, while the other expert testimony would pertain to technical aspects, the attorney's testimony would pertain primarily "to the complex law of patents, including the purpose of patents, patent office procedures and patent prosecution." *Id.* at *2. Here, too, Murray's testimony, preceded by the testimony of the scientific experts on stent technology, may assist the jury in understanding the evidence and determining the facts in issue.

Murray's testimony, if offered, "shall not include any exposition or opinion as to the legal issues in this case or patent law generally." *Ely v. Manbeck*, 17 U.S.P.Q.2d 1252, 1254 (D. D.C. 1990). Murray may explain his own understandings of the law and apply it to opinions of the scientific experts on the issues of fact, without giving expert opinions as to what the law is. *See Reiffin v. Microsoft Corp.*, 270 F. Supp.2d

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[11] Rule 702 of the Federal Rules of Evidence addresses testimony by experts and provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

1132, 1145 (N.D. Cal. 2003) ("Expert testimony of a patent attorney may be admitted, even if the attorney does not have specific expertise regarding the technical field involved in the litigation before the court, because the attorney's familiarity (or lack of familiarity) with that technical field bears on the weight to be accorded the evidence, not the threshold question of admissibility") (citations omitted); *Donnelly Corp. v. Gentex Corp.*, 918 F. Supp. 1126, 1137 (W.D. Mich. 1996) (denying motion *in limine* to preclude testimony by patent law expert, finding that "experts must walk a fine line: they must give their expert opinions on ultimate issues of fact, while explaining their own understandings of the law, but without purporting to give expert opinions as to what the law is"). The Court will provide any "necessary and appropriate instructions to the jury regarding the weight to be accorded to the testimony" after hearing Murray's testimony in light of the testimony of the other experts in the technical field. *Lemelson*, 1987 WL 26134, *2.

Furthermore, Murray may not offer opinions regarding claim construction, infringement, or any other issues of law. He may explain his understanding of the general requirements for entitlement to the benefit of an earlier-filed patent application under 35 U.S.C. § 120, including the meaning of an "effective filing date" and "new matter." He may offer opinions on the relevant background information regarding the patent application process. *See Buckley v. Airshield Corp.*, 116 F. Supp.2d 658, 662 (D. Md. 2000) (allowing patent attorney to testify to the procedures for prosecuting a patent, but precluding any rendering of legal opinions on claim construction and infringement). To the extent that AGR intends to elicit testimony from Murray concerning the general procedures involved in the patent application process, such testimony may be helpful to the jury, and is therefore admissible. *See, e.g., Bausch & Lomb, Inc. v. Alcon Laboratories, Inc.*, 79 F. Supp.2d 252, 255 (W.D. N.Y. 2000); *Revlon Consumer Prod. Corp. v. L'Oreal S.A.*, 1997 WL 158281, *3 (D. Del.

1997) (defendants' expert would be allowed to "testify only as to matters of PTO practice and procedure"); *Cameco Indus., Inc. v. Louisiana Cane Mfg., Inc.*, 1995 WL 468234, * 4 (E.D. La. 1995) (permitting expert to testify "about the patent application process, the operations and functions of the patent and trademark office, and the materiality of the relevant art"). Murray is also permitted to offer opinions regarding whether or not the invention disclosed in claim 2 of the '1,653 Patent is entitled to the benefit of the June 2, 1978 filing date of the '010 Application in accordance with 35 U.S.C. § 120, and he may respond to the conclusions reached in the expert reports of Drs. Puma and Laird that claim 2 of the '1,653 Patent is not entitled to the benefit of the 1980 filing date of the '989 Application or the 1978 filing date of the '010 Application. *See Bausch & Lomb*, 79 F.Supp.2d at 257 (permitting patent law expert to testify regarding the factual bases for his opinion on the effective filing date of a patent based on the testimony of scientific experts). Such testimony is relevant to the determination of whether the work of Dr. Palmaz constitutes prior art.

4. Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents

Cordis seeks to exclude the expert opinions of AGR's experts, Widas, Dr. Pope, and Dr. Leonard, on infringement under the doctrine of equivalents because these experts did not offer any opinions on the doctrine of equivalents in their expert reports or in their depositions. Cordis further argues that the declarations by AGR's experts that were submitted in response to Cordis' Motion for Summary Judgment are insufficient because they merely parrot the legal standard set forth in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U. S. 605, 608 (1950), without providing the detailed factual analysis that is necessary to show infringement under the doctrine.

With regard to Cordis' first argument, AGR's experts will be permitted to opine on the doctrine of equivalents at trial despite the untimely disclosure of the opinions. However, **at Cordis' request, AGR shall make its experts available for additional depositions by Cordis to probe their opinions relating to the doctrine of equivalents prior to trial.** Cordis' second argument for exclusion is rejected for the reasons provided *infra* on the Motion for Summary Judgment.

5. Cordis' Motion *in Limine* to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert*

Mr. Widas and Dr. Leonard have testified that after expansion of the balloon, Cordis' stents increase in rigidity to an infinitesimally small extent, which admittedly, they have not tried to measure. Cordis seeks to exclude this testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

There are conflicting expert testimony, literature, and other evidence, that bear on whether the opinions expressed by Mr. Widas and Dr. Leonard are true. On this record, the undersigned cannot determine that the scientific opinions expressed by Mr. Widas and Dr. Leonard are completely lacking in scientific reliability, as is required for expert testimony to be excluded under *Daubert*. It will the function of the jury to weigh the conflicting evidence and make credibility determinations, with proper instructions from the Court on the applicable law. Accordingly, the Motion *in Limine* to exclude Certain Testimony by Mr. Widas and Dr. Leonard is denied.

6. Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard

Cordis' Motion to Strike the Supplemental Report of Dr. Leonard is premised on the same grounds as Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents. For the rea-

sons previously outlined, this Motion is also denied. The Supplemental Expert Report of Edward F. Leonard is accepted as filed.[12]

C. CORDIS' MOTION FOR SUMMARY JUDGMENT, AND MOTION FOR CONSTRUCTION OF TERMS IN THE CLAIMS OF THE ROCKEY '1,653 PATENT

1. Legal Standard on Summary Judgment

Under Rule 56(c), Fed. R. Civ. P., a motion for summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The Supreme Court explained the movant's burden in *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986) as follows:

> In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.

Id. at 322. The Court further stated that "Rule 56(c) therefore requires a non-moving party to go beyond the pleadings and by [its] own affidavits or by the 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324.

By its very terms, this standard provides that the mere existence of "*some* alleged factual dispute between the parties

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[12] The Supplemental Expert Report of Dr. Leonard was filed as Exhibit 4 to Cordis' Motion to Strike, and as Exhibit A to AGR's Memorandum in Opposition to Cordis' Motion to Strike.

will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there will be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). An issue is "material" if it is a legal element of the claim under the applicable substantive law which might affect the outcome of the case. *Anderson*, 477 U.S. at 248; *Allen v. Tyson Foods*, 121 F.3d 642, 646 (11th Cir. 1997). An issue is "genuine" if the record taken as a whole could lead a rational trier of fact to find for the non-moving party. *Allen*, 121 F.3d at 646. On a motion for summary judgment, the Court must view all the evidence and all factual inferences drawn therefrom in the light most favorable to the non-moving party, and determine whether that evidence could reasonably sustain a jury verdict. *Celotex*, 477 U.S. at 322-23; *Allen*, 121 F.3d at 646.

While the burden on the movant is great, the non-moving party has a duty to present affirmative evidence in order to defeat a properly supported motion for summary judgment. *Anderson*, 477 U.S. at 252. A mere "scintilla" of evidence in favor of the non-moving party, or evidence that is "merely colorable" or "not significantly probative," is not enough. *Id.*; *see also Mayfield v. Patterson Pump Co.*, 101 F.3d 1371, 1376 (11th Cir. 1996) (conclusory allegations and conjecture cannot be the basis for denying summary judgment). Moreover, otherwise admissible evidence may be submitted in inadmissible form at the summary judgment stage. *See McMillian v. Johnson*, 88 F.3d 1573, 1584-85 (11th Cir. 1996); *Gaston v. Home Depot USA, Inc.*, 129 F.Supp.2d 1355, 1361 (S.D. Fla. 2001)

2. <u>Failure to Pay Royalties (Count I)</u>

a. *Patent Infringement Analysis*

There are two ways for a plaintiff to show patent infringement: literal infringement or infringement by equiva-

lence, referred to as infringement under "doctrine of equivalents." A literal infringement analysis involves two steps: (1) proper interpretation of the asserted patent claim(s) (*i.e.*, "claim construction") to determine their scope and meaning; and (2) comparison of the properly interpreted claim(s) and the defendant's product (*i.e.*, claim application) in order to determine whether the claims can be read onto the accused product. *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1207 (Fed. Cir. 2001); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580-81 (Fed. Cir. 1996). The first step, claim construction, is a question of law, while the second step, claim application (*i.e.*, the determination of "infringement") is a question of fact. *Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). However, literal infringement based on claim construction is amenable to resolution by summary judgment where the parties do not dispute the relevant facts regarding the accused product, but merely disagree over claim interpretation. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996); *Johnson v. IVAC Corp.*, 885 F.2d 1574, 1579-80 (Fed. Cir. 1989); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997). The patentee bears the burden of proving infringement by a preponderance of the evidence. *Advanced Cardiovascular Systems*, 261 F.3d at 1336.

In construing the patent claims, the trial court must discern the ordinary and customary meanings attributed to the words used. Standard dictionaries of the English language may help identify the ordinary meaning of a claim term. *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002); *Inverness Medical Switzerland v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1369 (Fed. Cir. 2002); *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334-35 (Fed. Cir. 2000). Once the court has determined the ordinary and customary meaning of the terms, there is a heavy presumption that those definitions are the proper

meanings. *Texas Digital Sys., Inc. v. Telegenix*, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art."). Thus, patent infringement analysis begins and must remain focused upon the words of the patent claims themselves to determine the ordinary and customary meanings of those terms. *Id.*

After the court has determined the ordinary and customary meanings of the terms at issue, it may then look to the rest of the intrinsic evidence, including the patent specification and file history. "[I]f an invention is disclosed in the written description in only one exemplary form or in only one embodiment, the risk of starting with the intrinsic record is that the single form or embodiment so disclosed will be read to require that the claim terms be limited to that single form or embodiment." *Texas Digital Systems*, 308 F.3d at 1205 ("'That a specification describes only one embodiment does not require that each claim be limited to that one embodiment.' ... Indeed, one can easily be misled to believe that this is precisely what our precedent requires when it informs that disputed claim terms should be construed in light of the intrinsic record.") (citing *Teleflex*, Inc., 299 F.3d at 1328); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995); *SRI Int'l, Inc. v. Matsuchita Elec. Corp.*, 775 F.2d 1107, 1121(Fed. Cir. 1985)). Therefore, "[a]lthough the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish or vary' the limitations in the claims." *Markman*, 52 F.3d at 979.

An analysis of the intrinsic record is particularly important because words often have multiple dictionary meanings. The intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is "most consistent with the use of the words by the inventor." *Texas Digital Systems*, 308 F.3d at

1203-04 ("'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'") (citing *Dow Chemical Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372-73 (Fed. Cir. 2001)); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, , 334 F.3d 1294, 1300 (Fed. Cir. 2003) ("[T]he general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context.... 'Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings. '") (citation omitted). "[T]he claims must be read in view of the specification, ... but limitations from the specification are not to be read into the claims." *Teleflex*, 299 F.3d at 1326. The file history must also be considered. *Id.* at 1324-25. "Among the intrinsic evidence, 'the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1325 (quoting *Vitronics*, 90 F.3d at 1582); *Markman*, 52 F.3d at 979 (Dictionary definitions are a useful first step, but "[c]laims must be read in view of the specification, of which they are a part."); *Bell Atlantic Network Serv. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) (The intrinsic evidence, *i.e.*, the surrounding claim language, the patent specification and the file history - provide "'the most significant source of the legally operative meaning of disputed claim language.'") (quoting *Vitronics*, 90 F.3d at 1582). Claims should be construed to encompass all definitions that are consistent with the use of the word in the intrinsic record, except those that have been disclaimed. *Brookhill-Wilk*, 334 F.3d at 1299 ("If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim may be construed to encompass all consistent meanings."); *see also Texas Digital*, 308 F.3d at 1203 (same).

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583 (citations omitted). There are only two situations where a sufficient reason exists to require the construction of a claim term to mean something other than its ordinary and accustomed meaning. The first occurs where the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term. *Vitronics*, 90 F.3d at 1582 ("Although words in a claim are generally to be given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.") (citing *Hoechst Celanese Corp. v. BP Chemicals, Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996)). The second arises where the term or terms chosen by the patentee so deprive the claim of clarity that there is "'no means by which the scope of the claim may be ascertained from the language used.'" *Bell Atlantic*, 262 F.3d at 1268 (citing *Johns[illegible] v. Worldwide Assoc. Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)). "Where a patentee has clearly defined a claim term, that definition is usually dispositive." *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1360 (Fed. Cir. 2002).

A court may also consider extrinsic evidence, such as expert testimony, as to how those skilled in the art would interpret the claims. However, a court should not rely on expert testimony or other extrinsic evidence if the intrinsic evidence establishes the proper construction of the claims. "I[f] an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence." *Brookhill*, 334 F.3d at 1304 (quoting *Vitronics*, 90 F.3d at 1582). The Federal Circuit has consistently emphasized that "extrinsic evidence," *i.e.*, anything outside of the intrinsic evidence - may not be used in claim construction to

vary the meaning of claim terms as reflected in the intrinsic record. *Vitronics*, 90 F.3d at 1583. In particular, "[e]xpert testimony ... may not [be used to] ... diverge from the description of the invention as contained in the patent documents." *Aqua-Aerobic Sys., Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1245 (Fed. Cir. 2000). Although the court may rely on the evidence from experts "to educate itself about the patent and the relevant technology, the claims and the written description remain the primary and more authoritative sources of claim construction." *Mantech Envtl. Cor. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998).

After the court has construed the claims of the patent, the properly construed claims must be compared to the accused device or method to determine whether the latter has "all of the claim limitations." *Techsearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002). To establish literal infringement, AGR must show that "every limitation set forth in a claim [is] found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). If any limitation is absent, there cannot be a finding of infringement.

If there is no literal infringement, a device or method may nonetheless infringe a patent under the doctrine of equivalents. *Sage Products, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997) ("A device that does not literally infringe a claim may nonetheless infringe under the doctrine of equivalents if every element in the claim is literally or equivalently present in the accused device."). One way that a plaintiff may show infringement under the doctrine of equivalents is by establishing that the offending device or method functions in substantially the same way to achieve substantially the same result as the device or method covered by the patent. *Graver Tank*, 339 U.S. at 608. Another way is by showing that the claim limitation or element is "equivalently present" in the accused device because there are only "insubstantial differences" between the missing claim limitation or

element and corresponding aspects of the accused device. *Zodiac Pool Care, Inc. v. Hoffinger Industries, Inc.*, 206 F.3d 1408, 1415 (Fed. Cir. 2000). Equivalence must be considered on a limitation-by-limitation basis; in other words, it must be determined whether **each** of the claim limitations are "equivalently present" in the accused product.

Although the doctrine of equivalents usually presents an issue of fact for the jury, "where the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

b. *Claim Construction and Application*

The following is an analysis of the language of claim 2 of the Rockey '1,653 Patent that begins with the ordinary dictionary meanings of the words provided by the parties and determines which of the ordinary meanings are consistent with the intrinsic record, and if more than one is consistent, then which meaning is most consistent with the surrounding words, the Patent specification and the file history. No extrinsic evidence has been considered in arriving at the proper construction of the claim terms. The Rockey invention disclosed by the properly construed claims is then compared to the Cordis stents.

i. The Proper Construction of the Terms of Claim 2 of the '1,653 Patent

"Introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated"

This claim limitation requires that a flexible tube of metal, rubber or plastic (the catheter) be inserted into a vessel, at a point remote from the area of the body to be treated (*i.e.*, the part where the sleeve ultimately will be placed and will remain), with a balloon and a sleeve that are both folded to-

gether compactly, and in such a way that the sleeve, which is capable of isolating material flowing into the vessel from direct contact with the interior surface of the vessel, surrounds the balloon and both the balloon and sleeve are positioned at or near an extremity of the catheter.

(a) Undisputed Terms

The parties agree that the following ordinary meanings of terms are consistent with the intrinsic record, and the Court adopts these meanings as consistent with the intrinsic record:

1. "Introducing" means *inserting or injecting.* (American Heritage Dictionary of the English Language (1980)) (hereinafter "American Heritage Dict.").

2. "Catheter" means *a "flexible tube of metal, rubber, or plastic inserted into a body channel, such as a vein, to distend or maintain an opening to an internal cavity.*" (American Heritage Dict.).

3. "Inflatable" means *capable of becoming inflated; swelling; expanding.* (American Heritage Dict.).

4. "Balloon" means "*[a]n elastomeric membrane completely enclosing a volume which expands when the volume of the fluid occupying that space or volume is increased, i.e. a rubber sack which may he inflated.*" (The Grosset Webster Dictionary (1966)).

5. "Vessel" means "*a tube or canal (as an artery) in which a body fluid is contained, conveyed or circulated.*" (Webster's Ninth New Collegiate Dictionary (1983)) (hereinafter "Webster's Ninth").

6. "Point" means "*a position, place or locality; spot.*" (American Heritage Dict.).

7. "Remote" means "*located far away; relatively distant in space.*" (American Heritage Dict.).

8. "Area" means "*any particular extent of space, surface, or region.*" (The Random House College Dictionary, Revised Ed. (1988)) (hereinafter "Random House").

9. "Treated" means *cared for or dealt with medically or surgically.* (Webster's Ninth).

(b) "Collapsed"

Cordis contends that a "collapsed" balloon or sleeve is a balloon or sleeve that has been reduced in bulk by being folded (*i.e.*, doubled over) into a more compact space. Cordis relies on the definition of "collapsed" as "[t]o fold compactly," provided in the American Heritage Dictionary of the English Language (1980). Cordis further relies on the definitions of fold as "to lay one part over another part of double upon itself' (Webster's Third New International Dictionary of the English Language Unabridged (1986)) (hereinafter "Webster's Third"), or "to reduce the length or bulk of by doubling over." (Webster's New Collegiate Dictionary (1981)). In contrast, AGR proposes the following definitions of "collapsed": (1) "[t]o fold or come together compactly;" (Webster's New Twentieth Century Dictionary (1977)) (hereinafter "Webster's Twentieth"); (2) "to fall together or in" (Webster's Twentieth); (3) "[t]o fold compactly" (American Heritage Dict.); (4) "[t]o be made so that parts can be folded, placed, etc., together" (Random House); and (5) "to fall or shrink together abruptly and completely; fall into a jumbled or flattened mass through the force of external pressure" (Webster's Ninth).

The Court has reviewed all of the foregoing dictionary definitions of the word "collapsed" in the context of the other words used in the '1,653 Patent, as well as the corresponding specification and file history. The surrounding text, specification and file history support the following construction of the word "collapsed," which is the one the Court adopts: folded together compactly so that one part is laid over another part. The following statements included in the Patent claim and

specification support such a construction of the word "collapsed" that is limited to materials that may be "folded" or "doubled over" to fit into a more compact space:

1. "[T]he sleeve is **sufficiently flexible** to be collapsed into a unit of relatively low bulk for- ease of passage through the posterior pharynx and esophagus." (Summary of the Invention, 2:19-23) (emphasis added).

2. "Fig[ure] 5 of a view of the sleeve unit in a **compacted** condition .." (Brief Description of the Drawings, 3:3-4) (emphasis added). Figure 5 is a drawing showing the disclosed sleeve with its parts folded compactly with some of it parts laying over or on other parts and contained in what is referred to as a "dilator shell or cup." Figure 6 shows the parts of the sleeve unfolding, or coming apart, after the dilator shell or cup is removed. Dr. Rockey describes the process in Fig. 6 as follows: "Lower sections of the filaments ... associated with the sheath [sleeve] 11 ... **unfold** themselves along with the sheath [sleeve]." (Description of the Preferred Embodiment, 4:24-27) (emphasis added).

3. "The sheath 11 [sleeve] in the illustrated example if [sic] a **flexible** membrane ..." (Description of the Preferred Embodiment, 3:24-25) (emphasis added).

4. Referring to Figs. 5, 6 and 7, Dr. Rockey instructed that "[t]o facilitate introduction of the sleeve unit 10 into the stomach 32, the sleeve unit is **folded on itself accordion fashion** to reduce its length and diameter." (Description of the Preferred Embodiment, 4:9-12) (emphasis added).

5. "In its **folded or compacted** state, the sleeve unit 10. . ." (Description of the Preferred Embodiment, 4:12-13) (emphasis added). Here, Dr. Rockey uses the words "folded" and "compacted" as synonyms.

6. In the preferred embodiment in Fig. 9, Dr. Rockey indicates that "[t]he collapsed state can be maintained by **wrapping the sleeve 51 on itself**," (Description of the Preferred Embodiment, 4:11-13; 6:43-44) (emphasis added), which is followed by insertion of the pressure of a liquid that inflates the balloon. "The pressure of this inflating fluid is sufficient to break the light heat bonds holding the **folds of the sleeve** ... together and to expand the sleeve . . ." (Description of the Preferred Embodiment, 6:48:51) (emphasis added).

7. "The balloon ... is formed of any suitable plastic or rubber material which may be **folded** and/or expanded." (Description of the Preferred Embodiment, 6:7-9) (emphasis added).

Thus, Dr. Rockey used the word "folded" to describe multiple drawings and embodiments disclosed in the '1,653 Patent, not just one preferred embodiment. The ' 1,653 Patent file history also uses the words "collapsed" and "folded" interchangeably. The instances where Dr. Rockey uses the words interchangeably are numerous and will not recited here, but one example may be found in Dr. Rockey's '010 Application. The '010 Application is similar to the '1,653 Patent in its description of the preferred embodiment of the sleeve as being "sufficiently flexible to be collapsed into a unit of relatively low bulk" for ease of delivery through narrow body passageways. As advanced by Cordis, the original claims of that application call for a sleeve that is "sufficiently flexible to be folded on itself to thereby reduce its bulk ... to facilitate initial placement of the sleeve into the body vessel." Although neither the word "fold" nor the phrase "folded on itself" was actually included in the language of Dr. Rockey's Patent claims, this language chosen by Dr. Rockey and included in his first application and throughout his three related patent file histories constitutes further evidence that when Dr. Rockey wrote "collapsed," he meant "folded," *i.e.*, "doubled over." Accordingly, the requirement that the balloon and the

sleeve must be "folded together compactly" may properly be read into claim 2 of the '1,653 Patent.

(c) "Sleeve"

Cordis argues that the term "sleeve" should be construed to cover an impervious liner, *i.e.*, one without holes or openings, suitable for isolating the wall of a body vessel from materials that otherwise could come into contact with it. Cordis cites to *Alloc, Inc. v. U.S. Int'l Trade Comm'n*, 2003 U.S. App. LEXIS 18744 (Fed. Cir.). The patent claims in *Alloc* did not mention a "play" or space between the components of the claimed locking joint, and "play" was not part of the dictionary definition of any claim term. Nonetheless, the Federal Circuit construed the claims as requiring "play" because the specification described "the invention" - not merely a preferred embodiment, but rather, the invention itself - as a locking joint with "play." *Id.* at 15. Moreover, the specification did "not show or suggest any systems without play." *Id.* at 18. Under these circumstances, the Federal Circuit construed the claims as requiring "play," even though "play" was not mentioned in the claims. As the Federal Circuit explained (*id.* at 19-20):

> [The] Court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. . . . [W]here the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.

See also SciMed Life Ins., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 2001) (discussed with approval in *Alloc*).

Throughout the '1,653 Patent specification, Dr. Rockey's invention - not merely a preferred embodiment, but the invention itself - is described as a sleeve that isolates a body vessel from material normally flowing into it. This theme starts on the first page of the Patent, when the Patent Abstract summarizes the '1,653 invention as "comprising a sleeve unit ... to **isolate material flowing into the vessel from direct contact with the interior surface of the vessel**." (emphasis added). The section of the '1,653 specification entitled "Summary of the Invention" goes on to describe Dr. Rockey's "invention" (again, not merely a preferred embodiment, but the invention itself) in the same fashion: "The invention provides a method and means for **isolating the internal walls of hollow viscera or other body vessels from contact with materials, both fluids and solids, occurring naturally, ingested or otherwise introduced into a body vessel**." (Summary of the Invention, 1: 54 58) (emphasis added). The "Summary of the Invention" further states that the "tissue isolating function of the disclosed sleeve," in addition to control of the mechanism of digestion, has numerous other applications . . ." (Summary of the Invention, 2:33-36). These include using the "sleeve . . to chemically and/or physically protect tissue which has been ulcerated, herniated, fissured, or the like from natural body fluids," *id.* at 2:37-40, which can be done by "isolating the effect of normal blood pressure from the vessel by containing it within the sleeve." *Id.* at 2:42-44. The Summary of the Invention also provides (*id.* at 1:58-64): "**Isolation of a body vessel according to the invention**, is achieved by positioning and anchoring a sleeve, impervious to materials sought to be isolated within the vessel ..." (emphasis added).

Every embodiment described in the Patent is capable of serving this "isolating" function. For example, the "sleeve unit" of the embodiment in Fig. 1, for use in the digestive system, is described as being "implanted in a body vessel in order **to isolate** the walls of such vessel from fluids normally flowing into it." (Description of the Preferred Embodiment,

4:1-3) (emphasis added). Figure 4 illustrates "a manner of use of the sleeve unit 10 **to isolate** the internal surface area or lumen, designated 31, of a human stomach 32 and its secretions from food substances passing through it." (*Id.* at 4:3-7) (emphasis added). The specification further states as to Fig. 4 that the sleeve reduces the digestive efficiency of the stomach "by **isolating** the walls 31 of the stomach 32 from ingested food passing through it ... ." (*Id.* at 5:6-8).

The other embodiments of the '1,653 Patent are described in similar terms. For example, an embodiment of the sleeve shown in Fig. 8 and intended for use in the aorta, is described as having "a construction essentially the same as the earlier described in sleeve 10." (Ex. 3 at 5:31-32). According to the specification, this permits "blood flowing through the sleeve [to be] effectively **isolated** from the vessel." (*Id.* at 5:55-56) (emphasis added). The remaining embodiment, shown in Fig. 9, is described as suitable for use in a body vessel requiring "**isolation** or like treatment." (*Id.* at 5:59-61) (emphasis added). The sleeve of this third embodiment has inner and outer walls that are capable of isolating the vessel wall because they are "imperforate" (*id.* at 6:10-11), and these imperforate walls are "joined in a fluidtight manner ...." (*Id.* at 6:12).

Each of the figures of the '1,653 Patent, and the only sleeves described in the Patent, show a sleeve that can isolate the vessel wall from materials with which it would otherwise come into contact. Indeed, the Patent does not disclose or suggest any embodiment of the sleeve that could not perform this "isolating" function. The term "sleeve" means the type of sleeve that Dr. Rockey described as his invention, *i.e.*, a part that can perform this tissue-isolating function.

AGR's experts take the position that the term "sleeve" should be defined as "a tubular part (such as a hollow axle or bushing) designed to fit over another part." (Webster's Ninth). This definition, however, does not comport with Dr. Rockey's

description of his "medical sleeve" in the '1,653 Patent. The definition of "sleeve" that the inventor adopted, implicitly or explicitly, in his specification is the one that should be given effect. As the Federal Circuit has held:

> [A] claim term may be clearly redefined [in the specification] without an explicit statement of redefinition. Indeed, we have specifically held that the written description of the preferred embodiments 'can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.'

Bell Atlantic, 262 F.3d at 1268 (quoting *SciMed Life Sys.*, 242 F.3d at 1344). "In other words, the specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" *Id.* (quoting *Vitronics*, 90 F.3d at 1584 n.6). *See also Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1367 (Fed. Cir. 2003) ("The applicant may also act as his own lexicographer and use the specification to implicitly or explicitly supply new meanings for terms.") (emphasis added); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003) (same); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1374-75 (Fed. Cir. 2003) (basing construction of the term "automation code" on the use of that term in the specification where dictionary definitions did not provide meaningful guidance on the usage of that term in the patent).

In *Bell Atlantic*, 262 F.3d 1258, for example, the Federal Circuit held that the patentee implicitly defined the term "mode" so that it had a narrower definition than the ordinary dictionary definition. Although the word "mode" had an ordinary meaning, the Federal Circuit did not end its analysis there. Instead, it went on to examine the specification:

> It may be true that the ordinary meaning of the word 'mode' supports a broader meaning than the construc-

> tion ascertained by the district court. However, we must look at the intrinsic evidence to determine whether the patentee has given the term an unconventional meaning.

Id. at 1269. In construing the claims, the Federal Circuit relied extensively on the patentee's repeated references to the purpose of the invention, including those in the summary of the invention. *Id.* at 1269-73. Based on the implicit definitions in the specification, the court construed the term "mode" to be limited to the embodiments actually disclosed in the specification and not to the broader ordinary meaning (*id.* at 1273):

> We acknowledge that it is generally impermissible to limit claim terms by a preferred embodiment or inferences drawn from the description of a preferred embodiment.
>
> However, that is not the case here. We note that '[t]he usage 'preferred' does not of itself broaden the claims beyond their support in the specification.' Moreover, unlike *Johnson v. Worldwide*, this case does not involve the '[v]aried use of a disputed term.' Instead, the patentees defined the term 'mode' by implication, through the term's consistent use throughout the '786 patent specification. Given this definition, the three modes described in the Detailed Description of the Preferred Embodiments describe the three possible modes of the invention, and the claims are not entitled to any broader scope.

The '1,653 specification as a whole is replete with descriptions of Dr. Rockey's "sleeve" as capable of isolating the vessel wall from contact with materials. That definition is one that Dr. Rockey implicitly or explicitly adopted, and it governs. *See Bingo Brain, Inc. v. Cal. Concepts, Inc.*, 2002 WL 99272, at *3-5 (N.D. Ill. 2002), *aff'd* 53 Fed. Appx. 75 (Fed. Cir. 2002) (court relies on implicit definition in specification

to limit claim term "bingo cards" to physical bingo cards and not to include virtual bingo cards); *Wang Lab, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999) (claim term interpreted more narrowly than its ordinary meaning and limited in accordance with the specification, which described a particular feature as part of the invention); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295 (Fed. Cir. 1999) (claim term interpreted in accordance with specification and drawings, which showed a particular structure, did not illustrate or describe any other structure, and described the advantages of the featured structure as important to the invention); *Chiron Corp. v. Genentech, Inc.*, 266 F.Supp.2d 1172, 1198 (E.D. Cal. 2002) (inventor acted as his own lexicographer of "immunoassay" based on the purposes of the patent").

Nevertheless, and contrary to the position adopted by Cordis, Dr. Rockey did not require that the sleeve be completely "impervious." Although he makes several references to the "sleeve" as an "impervious" liner, he does not describe it in such a way in the Abstract section of the Patent specification. As previously mentioned, he does specify in the Abstract that the sleeve unit must isolate material flowing into the vessel from direct contact with the interior surface of the vessel. Although an impervious material would accomplish the "isolating" function, it is conceivable that a device that is not completely impervious could nonetheless isolate some materials from the vessel. Moreover, the term "impervious" is not used to describe all of the preferred embodiments. The critical aspect of Dr. Rockey's invention is the "tissue isolating function," as it is described as the only feasible design in the disclosure. As far as the "shape" of the "sleeve," Dr. Rockey provides that it may be cylindrical, tubular, or "it may take other configurations, such as a frustum or a sphere truncated adjacent opposite poles, or a tubular elbow of constant and varying diameter." (Description of the Preferred Embodiment, 3:39-44).

AGR relies on the section of the Patent specification that provides that "the sleeve can include a weave or mesh outer layer (not shown) which will lie against and adhere to the wall to the blood vessel." (Description of the Preferred Embodiment, 6:17-21). In this sentence, Dr. Rockey refers to the "outer layer" of the sleeve, which may be made of weave or mesh. Dr. Rockey also writes, however, that "[t]he inner wall 61 may be formed of Teflon so that cells will not readily adhere to this area." (*Id.*). Accordingly, the sleeve's inner layer performs the isolating function in this embodiment.

AGR does not deny that the specification of the '1,653 Patent describes Dr. Rockey's invention as a sleeve that can isolate the wall of a body vessel from material that otherwise would come into contact with it. Nor does it deny that every embodiment in the Patent is capable of performing that isolating function. And AGR cannot point to any different use of the term "sleeve" in the '1,653 Patent. The term "sleeve" accordingly should be given the meaning it has in the specification of Dr. Rockey's Patent.

Because the specification of the '1,653 Patent describes Dr. Rockey's "invention" - not just a preferred embodiment, but the invention itself as a sleeve that can isolate the wall of a body vessel from material that otherwise would come into contact with it, the Court will adopt the meaning attributed by Dr. Rockey to his invention. Thus, a "sleeve" refers to *a cylinder, tube, frustum or sphere insertable into a body vessel and capable of isolating material normally flowing into the vessel from direct contact with the interior surface of the vessel.*

(d) "Encircling the Balloon on its End"

There appears to be no dispute regarding the meaning of the word "encircling." The following construction agreed to by the parties, which is consistent with the intrinsic evidence, is therefore adopted:

"Encircling" means forming a circle around; surrounding." (Webster's Ninth).

Here agreement ends. Cordis argues that this limitation requires that the sleeve must be positioned at the balloon's "extreme or last part lengthwise," which is one definition of "end" provided in Webster's Ninth New Collegiate Dictionary. AGR argues that the following other definitions of the word "end" also provide a proper construction: (1) "the part **at, toward, or near either of the extremities** of anything; tip" (Webster's Twentieth); (2) "[e]ither extremity of something that has length" (Random House); (3) "[t]he outside or extreme edge or limit of a space, form, or event; a boundary" (Random House); (4) "a part or place **at or adjacent to an extremity**" (Webster's Ninth) (emphasis added); (5) "the part of an area that **lies at the boundary**" (Webster's Ninth).

The parties also dispute whether "on its end" refers to the end of the balloon, which is Cordis' construction, or the end of the catheter, AGR's construction. According to AGR, this limitation indicates that the catheter has both a collapsed inflatable balloon and a collapsed sleeve encircling the balloon **on the end of the catheter**. That is, the claim requires that each of those two elements - the collapsed balloon and the collapsed sleeve- be "on its end," referring to the catheter; otherwise, there would be no information as to where the inflatable balloon is located on the catheter. Thus, AGR argues, that, when properly read, the phrase indicates that this element of the claim includes a catheter that has both a collapsed inflatable balloon and a collapsed sleeve located at the end of the catheter.

Figure 9 from the '1,653 Patent specification shows that the sleeve and the balloon are both located at the extreme or last part lengthwise of the catheter, and not at or near an extremity. This picture of one preferred embodiment is the only intrinsic evidence that supports the meaning of end as "the extreme or last part lengthwise." There is no language in the

Patent itself or in the specification or history that limits explicitly or implicitly the meaning of end to "the extreme or last part lengthwise." Therefore, the Court will not construe the term to include such a limitation.

Based on the drawing in Fig. 9, the disclosed sleeve encompasses or covers the balloon, but is not on the end of the balloon; that is, the sleeve in the disclosed embodiment is located over the balloon and not at either end of the balloon. Moreover, there is other evidence contained within the specification that renders the "on its end" limitation applicable to the end of the catheter rather than the end of the balloon. In the description of the embodiment depicted in Fig. 9, Dr. Rockey wrote "catheter 54 having a dilator annular balloon 50 **at its free end** [the end of the catheter that is not being "manipulated" by the user of the invention as indicated in the next claim limitation: "manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated"] and the sleeve 51 surrounding the balloon is threaded through the vessel 52 from an incision made in the vessel..." (emphasis added). Here, too, he describes a catheter having a balloon and a sleeve on the "free end" of the catheter.

The construction of the term "end" that is most consistent with the surrounding text and the specification is *the part at, toward, or near an extremity lengthwise*. Accordingly, the phrase "encircling the balloon on its end" requires that the sleeve encircle the balloon on a part at, toward or near an extremity of the catheter.

"Manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated"[13]

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[13] The Court finds that the inventor attributed the same meaning to a particular term every time it appears in claim 2. Therefore, where a term has been previously construed, such as in this case the terms "catheter," "ves-

Cordis argues that based on the ordinary meaning and intrinsic evidence, this claim limitation requires someone to handle the catheter so that the balloon and sleeve move through the vessel until the balloon and sleeve are in the region to be treated. Cordis' construction is based on the definitions offered by AGR and used by AGR's experts in their analysis. In its briefs, AGR has not offered a proposed construction of this phrase. The only dispute between the parties with regard to this claim limitation is that Cordis argues that the Court must choose the meaning for each term that is **most consistent** with the Patent and its history, while AGR maintains that the Court must adopt every proposed meaning because all are consistent. Not only does the law require that the Court choose the most consistent meaning as its claim construction, see supra, but this makes the most sense since offering a jury six or seven definitions or meanings of a term would not provide meaningful guidance.

The following ordinary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

1. "Manipulating" means "*treating or operating with the hands or by mechanized means in a skilled manner.*" (Webster's Ninth).

2. "Axially" means *in the direction of a central line bisecting a body, form or the like*. (Random House).

3. "Enter" means "*to go or come in.*" (Webster's Ninth).

Accordingly, this claim limitation requires someone to handle the catheter with his or her hands so that the attached balloon and sleeve move through the vessel until the balloon and sleeve are in the region to be treated.

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sel," "balloon," "sleeve," "area" and "treated," the construction applies as to each claim limitation containing the term.

"Inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel"

Once again, the parties do not dispute that all of the dictionary definitions offered by AGR are consistent with the intrinsic record. The only question is how many meanings should be attributed to the terms, and which meaning for each term is most consistent with the words of the inventor in the Patent specification and file history.

The following ordinary dictionary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

1. "Inflating" means *distending, swelling or puffing out.* (Random House).

2. "Fluid" means "*[a] substance, as a liquid or gas, that is capable of flowing and which changes its shape at a steady rate when acted upon by force.*" (Random House).

3. "Pressure" means "*[t]he application of force to something by something else in direct contact with it.*" (Webster's Ninth).

4. "Tube" means "*[a] hollow elongated cylinder.*" (Webster's Ninth).

5. "Manner" means "*way of doing, being done, or happening.*" (Random House).

6. "Surrounding" means *enclosing on all sides; encompassing; forming an enclosure around; encircling.* (Random House).

7. "Radially" means "*[m]oving in the direction of a radius; going from the center outward or from the circumference inward along a radius.*" (Random House).

8. "Expanded" means *opened up; increased in extent, number, volume or scope of opened out.* (Webster's Ninth).

9. "Towards" means "*[i]n the direction of.*" (Random House).

10. "Wall" means "*[a] material layer enclosing space.*" (Webster's Ninth).

Accordingly, this claim limitation requires the insertion under force of a fluid substance into the balloon through a tube of the catheter causing the balloon and the sleeve encompassing or enclosing the balloon to increase in extent, size or volume in the direction of a radius and in the direction of a layer of the vessel that is being treated.

"Providing in the sleeve a material which increases in rigidity after expansion of said balloon"

(a) "Providing in the Sleeve a Material"

The meaning of the term "material" is undisputed. Therefore, the following ordinary meaning of "material" is adopted as the one that is most consistent with the intrinsic record: "*[t]he substance or substances of which a thing is made or composed.*" (Random House).

The words "providing" and "in" are the terms in dispute. Cordis argues that this limitation requires the act of supplying in a materially bounded object, *i.e.*, the sleeve, a material that is separate and distinct from the sleeve itself. AGR argues that Cordis seeks to wrongfully limit this phrase by contending that it requires providing in the sleeve an *additional* material that increases in rigidity. AGR's proposed construction is that the claim limitation requires that the sleeve itself, or alternatively, an additional material added to the sleeve, be made of a material that increases in rigidity.

Cordis proposes that the meaning of "provide" is "to supply or make available; to make something available to" (Web-

ster's Ninth), and the word "in" "indicate[s] location in space or in some materially bounded object." (Webster's Third). Thus, according to Cordis, the claim limitation requiring the step of "providing in the sleeve a material which increases in rigidity" requires the act of supplying in a materially bounded object (*i.e.*, the sleeve) a material that is separate and distinct from the sleeve itself.

AGR relies on the following definitions of "provide," all of which it claims are consistent with the use of the word in claim 2: (1) "to make available;" or "to supply; to afford" (Webster's Twentieth); (2) "to furnish, supply, or equip;" "to afford or yield;" or "to prepare or procure beforehand (the latter being referred to as an "archaic" meaning)" (Random House); and (3) "to make preparation to meet a need;" or "to supply or make available" (Webster's Ninth). With regard to the term "in," AGR relies on the following dictionary definitions: (1) "contained or enclosed by, inside; within;" or "amidst; surrounded by;" or "into;" or "limited by the scope of" ("as, *in* my opinion"); "so as to form" ("as, arranged in curls"); "with; by; using" ("as, he paints *in* oil" and "written *in* English"); "made of" ("as, it was done *in* wood"); "by way of" ("as, do this *in* my defense") (Webster's Twentieth); (2) "[w]ithin the confines of; inside;" or "[w]ithin the area covered by" (American Heritage Dict., p/ 663); (3) "used to indicate inclusion within space, a place or limits;" or "on the inside; within" (Random House); (4) "to or toward the inside, esp. of a house or other building;" or "within a particular place;" or "that is located inside or within" (Webster's Ninth); (5) "by means of: with (written *in* pencil)"; or "used as a function word to indicate manner, state, or situation (alike in some respect) (left *in* a hurry)" (Webster's Intermediate Dictionary (1977)) (hereinafter "Webster's Intermediate"); and (6) "existing as a part, characteristic, or property of (*in* the works of Shaw);" or "made of a specified color, style or material;" or "for the purpose of (to run *in* pursuit);" or "by means of (speaking *in* whispers);" or "with regard or respect to (stu-

dents vary *in* talent)" (Funk & Wagnalls Standard Desk Dictionary (1976)) (hereinafter "Funk & Wagnalls").

Cordis indicates that the sleeve of the Fig. 9 embodiment in the specification has "inner and outer walls" (preferably made of Dacron or Teflon), and a separate fluid material is provided in the interior space between the inner and outer walls of the sleeve. (Description of the Preferred Embodiment, 6:11-14). Optionally, this material is provided in the sleeve just before the sleeve is introduced in the vessel, (id. at 6:35-40), but alternatively, it may be provided in the sleeve later, through a tube. (Id. at 7:7-10). Either way, the material that is being "provided in the sleeve" is separate from the sleeve itself according to Fig. 9. The Court has given Fig. 9 particular consideration because, as stressed in Cordis' Motion for Reconsideration (D.E. 165), it is the only embodiment that Dr. Rockey added in his application for the' 1,653 continuation-in-part patent, along with Claims 1 and 2 of that patent. Moreover, it is the only embodiment that practices all of the limitations of Claim 2.

Claim 2, consistent with the embodiment in Fig. 9, refers to a separate and distinct material that is "provided in" the sleeve. However, when Dr. Rockey wanted to describe what material the sleeve would consist of, he knew how to do so. Within the same '1,653 Patent containing Claim 2 and corresponding Fig. 9, in the description of the structurally different embodiment depicted in Figs. 1 through 7, Dr. Rockey described the sleeve as "formed of' a material. (Description of the Preferred Embodiment, 5:52-56). Dr. Rockey wrote:

> The **sleeve 25 is preferably formed of** relatively inelastic material or otherwise is circumferentially reinforced with inelastic material along its length so that the pressure of blood flowing through the sleeve is effectively isolated from the vessel.

(*Id.*) (emphasis added). There is nothing in the record to suggest that Dr. Rockey used the phrases "provided in" and

"formed of" interchangeably. The embodiment in Figs. 1 through 7 had been incorporated into Dr. Rockey's prior patent. Subsequently, in drafting Claim 2, Dr. Rockey purposefully chose the words "provided in" as opposed to "formed of" and, at the same time, conceived of Fig. 9 as an embodiment of Claim 2.

AGR argues that claims may be broader than any of the disclosed embodiment(s). (Plaintiff's Supplemental Response to Defendant's Motion for Reconsideration, p. 1). While this is true, the Court finds that the intrinsic record taken as a whole supports Cordis' construction. Accordingly, the claim construction of the phrase "providing in the sleeve a material" is: *to supply in the sleeve a material that is separate and distinct from the sleeve itself.*

(b) "Increases in Rigidity After Expansion of Said Balloon"

The meaning of the term "increases" appears to be undisputed. Therefore, the following ordinary meaning of "increases" is adopted as consistent with the intrinsic record: *becomes progressively greater in size, amount, number or intensity.* (Webster's Ninth).

Cordis contends that "rigid" means "[d]eficient in or devoid of flexibility" (Webster's Ninth); or "stiff or unyielding; not pliant or flexible," or "firmly fixed or set" (Random House). Cordis' selected definition for "expansion" is "the act or process of expanding" (Webster's Ninth), and "after" means "following in time" (Webster's Third). Cordis' position is that under the ordinary meaning of the claim language, the material that is provided in the sleeve must increase in rigidity, *i.e.*, become more stiff and less flexible, and this increase in rigidity must take place *following* the act or process of expanding the balloon. Cordis argues that these definitions are consistent with the surrounding text, because the next step in the claim 2 method involves the act of "maintaining said balloon in an expanded condition in the vessel while said

sleeve increases in rigidity." According to Cordis, the language used in that step confirms that an increase in rigidity must take place following expansion of the balloon.

AGR has asked the Court to consider the following definitions of "rigidity": (1) "deficient in or devoid of flexibility;" or "appearing stiff and unyielding" (Webster's Ninth); (2) stiff or unyielding; not pliant or flexible; hard;" or "firmly fixed or set" (Random House); (3) "not easily bent; inflexible" ("as, *rigid* in death"); or "not moving; firmly fixed; set;" or "not deviating or relaxing; rigorous" ("as, *rigid* regulations") (Webster's Twentieth); (4) "lacking flexibility; stiff hard; inflexibility set; unyielding" (Webster's Intermediate); (5) "resisting change of form; stiff severe; fixed" (Funk & Wagnalls); (6) "the quality or state of being rigid" (Webster's Ninth) (defining "rigidity").

AGR maintains that by arguing that this limitation requires an increase in rigidity after the full or complete expansion of the balloon, Cordis seeks to limit the claim terms. There are multiple dictionary definitions for the phrase "after," all of which are consistent with the use of the word in claim 2. For example, AGR offers that Webster's Twentieth defines "after" as" "later in time" and "according to the direction and influence of." AGR argues that this limitation is satisfied as long as there is some increase in rigidity after any expansion of the balloon, even if the doctor is still in the process of expanding the balloon. Cordis responds that this interpretation confuses "after" with "during."

The Patent, specification and file history have been examined to determine the meanings of the words "rigidity," "after" and "expansion" in context. There is no language or other evidence that requires that the balloon be fully expanded before the material in the sleeve starts to increase in rigidity. Dr. Rockey describes, with respect to the preferred embodiment depicted in Fig. 9, that "[t]he sleeve space 63 contains a fluid plastic material 66 which is caused to become solidified,

preferably to a semirigid state after the balloon has been expanded." (Description of the Preferred Embodiment, 6:22-24) (emphasis added). He also wrote that "[t]he inflation pressure is maintained for a period sufficient for setting of the liquid 66 in the sleeve space 63 to become solidified into its semirigid state." (*Id.* at 6:52-54). And, he disclosed that "[a]fter the sleeve material has solidified into a semirigid structure, the balloon is deflated through the catheter." (*Id.* at 6:57-59). Finally, he wrote:

> It is contemplated that the catalyst for setting of the material 66 can be encapsulated and mixed with the base and caused to release from such encapsulation upon the pressure applied thereto by **expansion** of the balloon 50. Another alternative is to introduce the settable material 66, including mixed catalyst, into the space through the tube 64 after the sleeve has been manipulated into position.

(*Id.* at 7:3-10) (emphasis added).

At no point during this discussion does Dr. Rockey require that the balloon be fully expanded before **any** increase in rigidity takes place in the sleeve, especially considering that the trigger that causes the catalyst to begin the process of making the sleeve rigid is the first expansion of the balloon. Dr. Rockey specifically discusses how the sleeve material does not achieve a semirigid state until after the balloon has expanded (past tense), but this does not mean that there was no increase in rigidity while the balloon was expanding. Full expansion is not required for there to be an increase in rigidity. The progressive change in rigidity begins to occur as soon as the balloon begins to expand, which is what sets of the catalyst.

Dr. Rockey's use of the word "expansion" rather than "expanded" is telling. In describing the increase in rigidity, he refers to the process of "expansion" of the balloon, which is followed by the increase in rigidity of the sleeve material. In

other parts of the specification, however, Dr. Rockey refers to a "fully expanded" sleeve (Brief Description of the Drawings, 3:9-11; 4:52). This suggests that had he meant "fully expanded," he would have said so.

The next step in the claim 2 method involves the act of "maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity." Contrary to Cordis' assertions, this step does not confirm that an increase in rigidity must take place following complete expansion of the balloon. The increase in rigidity takes place after the balloon begins to expand, and once the balloon has been fully expanded, the balloon is maintained in the inflated condition while the sleeve achieves the semirigid state required before the balloon may be removed. That is how Dr. Rockey described the process involved in his invention, and therefore, that is how the claims are to be interpreted.

The ordinary meanings of "rigidity" and "after" that are most consistent with the intrinsic record are as follows:

1. "Rigidity" means *the quality or state of being deficient in or devoid of flexibility, stiff and unyielding, hard, or firmly fixed or set.* (Webster's Ninth; Random House).

2. "After" means "*following in time.*" (Webster's Third).

3. "Expansion" means "*[t]he act or process of expanding.*" (Webster's Ninth).

Accordingly, the phrase "increases in rigidity after expansion of the balloon" requires that the *material added to the sleeve during the procedure increase in rigidity after the balloon begins to expand.*

"Maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity"

Based on the preceding discussion of the meaning of the phrase "increases in rigidity after expansion of the balloon," the following ordinary meanings of the terms in this subsequent step in a sequence of procedures are the most consistent with the intrinsic record:

1. "Maintaining" means *keeping in an existing state.* (Webster's Ninth).

2. "Condition" means "*existing state.*" (Random House).

3. "While" means "*during the time that.*" (The American Heritage Dictionary, Second College Ed. (1982)).

Accordingly, this claim limitation requires keeping the balloon in its expanded state after the balloon has fully expanded while the sleeve increases in rigidity to the point of attaining a semirigid state.

"And thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated"

The following ordinary dictionary meanings offered by AGR, and adopted by Cordis, are the meanings that are most consistent with the intrinsic record:

1. "Thereafter" means "*[a]fter that in time or sequence; afterwards.*" (Random House).

2. "Removing" means *moving from a place or position.* (Random House).

3. "Allowing" means *permitting something to happen or exist.* (Random House).

4. "Remain" means "*[t]o stay in the same place.*" (Webster's Ninth).

5. "Place" means "*[a] particular part of a surface or body.*" (Webster's Ninth).

Accordingly, this limitation requires that, after the other five preceding steps of the method claim are performed, the user remove the catheter and the balloon from the vessel while contemporaneously leaving the sleeve in the same position in the area to be treated.

ii. Application of the Properly Construed Claim 2 to the Palmaz Stent Sold by Cordis

The first step of claim 2 of the '1,653 Patent requires "introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated." Based on the preceding construction, there are genuine issues of material fact precluding a summary judgment of non-infringement in favor of Cordis, including but not limited to: whether Cordis' stents are folded together compactly so that one part is laid over another part (*See, e.g.*, Leonard Depo., 94:3-10; 95:12-15; 96:1-4; 103:7-25; 104; 105; 108:24-25; 109:1-10) (the Cordis stent is "folded compactly" and doubled over with one part lying over another part); Puma Decl. ¶¶ 20-22 ("[I]ts [Cordis'] stents are not 'folded,' that is, no part of the stent is laid over another part. The stent is never doubled upon itself"); Widas Depo., 92:21-24; 93:1-4 (the Cordis stent is not "bent upon itself"); whether the Cordis stent encircles the balloon at or near the end of the catheter (Leonard Depo., 111:11-25; 224:10-20) (Cordis' stent is located near the end of the catheter); Puma Decl., ¶¶ 23-29) (Cordis' stent is not located at or near the end of the catheter; rather, it is located "at a distance"); Majercak Decl., 116-8 ("Cordis' stents and the balloon on which they are mounted are positioned so that the end of the catheter extends a distance beyond the stent and balloon. ")); and whether the Cordis stent is a "sleeve." Although it seems unlikely that the Cordis stents could be a "sleeve" as disclosed by Rockey based on the undisputed fact that these stents have holes or openings, the technical experts have not opined on whether the Cordis stents are nonetheless

somehow capable of isolating body vessels from some materials that would normally come in contact with the vessels. Because no evidence has been presented on this issue, summary judgment is inappropriate.[14]

The second step requires "manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated." The third step envisions "inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the sleeve is radially expanded towards the wall of the vessel." The fourth step involves "providing in the sleeve a material which increases in rigidity after expansion of said balloon." The fifth step requires "maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity." Finally, the sixth step of claim 2 requires "thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated." As to all of these steps, and based on the Court's construction, there are issues of fact precluding summary judgment, including but limited to, whether the Cordis stent is a "sleeve" as that term has been construed by the Court.

c. *The Doctrine of Equivalents*

As a threshold issue, the undersigned addresses Cordis' position that AGR may not rely on the doctrine of equivalents to show infringement because the AGR experts have not provided sufficient evidence of infringement under the doctrine. Cordis argues that Dr. Leonard's Supplemental Report, and the Pope, Widas and Leonard declarations filed in response to Cordis' Motion for Summary Judgment, fail to address the basics of the doctrine of equivalents analysis. It is suggested that AGR's experts never compare the way in which the ac-

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[14] Moreover, Cordis has not moved for summary judgment based on the meaning of the term "sleeve."

cused product and the sleeve of Dr. Rockey's invention perform any relevant function. In particular, Cordis contends that they never compare the way in which Cordis' stents and the sleeve of Dr. Rockey's invention increase in rigidity.

"Equivalence, in the patent law, is not a prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect." *Graver Tank*, 339 U.S. at 609; *National Presto Industries, Inc. v. The West Bend Company*, 76 F.3d 1185, 1191 (Fed. Cir. 1996). No specific formulation of evidence and argument is required to prove equivalence. *National Presto Industries, Inc.*, 76 F.3d at 1191 (citations omitted); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997) ("In our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts.").

In appropriate cases, the function-way-result test offers guidance on the question of equivalence. Under this test, the fact finder determines whether the element in the accused device does substantially the same thing in substantially the same way to get substantially the same result as the claim limitation. *The Toro Company v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001). Another appropriate test is the "insubstantial differences" test. *Id.* Under this test, equivalency may be found where the difference in the accused device is facially "unimportant and insubstantial." *Id.* Similarly, an accused device may infringe where it lacks an insignificant function of a single claim limitation. *Id.* at 1371.

In order to prove infringement under the doctrine of equivalents, patentees must present evidence showing how each claim limitation is present by a substantial equivalent in

the accused device, and this must be shown through "particularized testimony and linking argument." *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567(Fed. Cir. 1996); *see Hewlett-Packard Co. v. Mustek Sys., Inc.*, 2003 WL 21804808, * 6 (Fed. Cir. Aug. 7. 2003) (citation omitted). The testimony must be presented on a limitation-by-limitation basis. That is, in order to provide the jury with "guiding charts when called upon to determine infringement under the doctrine [of equivalents]," the patentee should present "particularized testimony" of witnesses and "linking argument" by counsel. *Lear Siegler, Inc. v. Sealy Mattress Company of Michigan, Inc.*, 873 F.2d 1422, 1425-26 (Fed. Cir. 1989); *see Nestier Corp. v. Menasha Corp.*, 739 F.2d 1576, 1579-80 (Fed. Cir. 1984). While generalized testimony as to the overall similarity between the claim and accused device is insufficient, the patentee need only show "how the patented and the accused device were constructed and operated, overall as well as with respect to each claim element." *National Presto Industries, Inc.*, 76 F.3d 1185 at 1191. Conclusory assertions that an accused product performs the same function in the same way to achieve the same result are not enough. *Hewlett-Packard*, 2003 WL 2184808, at *6.

Cordis contends that Dr. Leonard's Supplemental Report fails to meet these basic requirements because it only offers conclusory assertions. For example, Cordis proffers that all Dr. Leonard does is parrot the tripartite test from *Graver Tank*, 339 U.S. at 608, by asserting that metal stents and polymer stents function in substantially the same way to achieve substantially the same result. Admittedly, mere recital of the *Graver Tank* mantra without more, is not enough to create a genuine issue of material fact as to whether an accused device infringes by equivalents. *See, e.g., Techsearch, L.L.C v. Intel Corp.*, 286 F.3d 1360, 1371-72 (Fed. Cir. 2002); *Moore US.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1113 (Fed. Cir. 2000). Moreover, Cordis argues, Dr. Leonard also misses the mark by comparing a generic "poly-

mer stent" with a stent made of 316L stainless steel. The proper comparison under the doctrine of equivalents would be a limitation-by-limitation comparison between the accused products and the sleeve of Dr. Rockey's invention.

Cordis' position is unavailing. A review of the expert testimony shows that AGR's experts have conducted an element-by-element analysis of claim 2 of the '1,653 Patent in their expert reports. In each instance where AGR's experts addressed the respective claim elements in their testimony they did not limit their opinions to literal infringement. For example, in his Supplemental Expert Report Dr. Leonard asserts, as to each disputed claim limitation, that the polymer sleeve patented by Dr. Rockey functions in the same way to achieve substantially the same result as the Cordis stainless steel stent. During the Pope deposition, Dr. Pope also indicated that some of the facts supporting the AGR experts' opinions regarding the doctrine of equivalents is that a stent made of stainless steel functions in substantially the same way to achieve substantially the same result as a stent made out of polymer. Thus, AGR's experts have testified that a stent made of stainless steel, which is plastically deformed during expansion, functions in substantially the same way to achieve substantially the same result, as a stent made by a polymer which undergoes polymerization and hardening upon expansion.

Most importantly, Dr. Leonard's Supplemental Report incorporates by reference his two earlier reports. In his initial report, Dr. Leonard details, on an element by element basis, how the Cordis stents are constructed and operate. In terms of the "way" the Cordis stents are used, Dr. Leonard relies upon the instructions provided with the medical sleeve. Dr. Leonard also explains in his first report how the methods set forth in claim 2 of the '1,653 Patent would be understood by one skilled in the art, how the Cordis stents are used and function, the intended result of their use, and the way in which they achieve those results.

Specifically, in his initial report Dr. Leonard concludes that "to a reasonable degree of engineering certainty ... based upon my review of the Accused Products [Cordis' stents] and the method by which those products are specified for their use as described in the instructions provided, and with the devices furnished for their placement, ... the accused device meets every limitation of claim 2 of the '1,653 Patent." (Leonard Expert Report, ¶ 35). On an element-by-element basis, Dr. Leonard further explains how each step of the Rockey method claim is practiced in the Cordis stents. In terms of their function, Dr. Leonard explains that the Cordis stents are "used for introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve or stent encircling the balloon on its end into a vessel at a point remote from the area to be treated. For instance, the coronary stent is inserted in the femoral artery which is remote from the coronary arteries, which is the area to be treated." Further, the Cordis stents, like Rockey's method claim, are designed to "resist compressive stresses that tend to collapse" stents and "to allow the sleeve and stent to remain in place in the area to be treated." Dr. Leonard explains that the way this is accomplished is by inserting the Cordis stents into a vessel at a point remote from the area to be treated, and then manipulating the catheter axially along the vessel causing the balloon and stent to enter the area to be treated. He further explains that the balloon is then inflated by introducing fluid under pressure into the balloon through a tube of the catheter in a manner in which the Cordis stent surrounding the balloon is radially expanded toward the wall of the vessel.

After being expanded in the area to be treated, the "way" in which the Cordis stents are able to remain in place and resist compressive stresses is that they "have a material in the sleeve which increases in rigidity after expansion of the balloon." In particular, Dr. Leonard explains that "the stainless steel utilized in the stent or sleeve is internally strengthened by plastic deformation within each of its elements," and "is

also strengthened in its entirety by reorientation of its elements with respect to each other from an internal, predominantly axial orientation to a final, more circumferential position." Finally, the method for using the Cordis stents requires that the balloon and catheter be removed, leaving the stent in place in the area to be treated.

Dr. Leonard also states in his initial report that all of the referenced methods for using the Cordis stents are within the limitations of claim 2 of the '1,653 Patent. He explains or interprets claim 2 of the '1,653 Patent. In particular, if claim 2 of the '1,653 Patent were construed to be limited to polymer stents, Dr. Leonard explains that a polymer stent functions in substantially the same way to achieve substantially the same result as the Cordis stents made of 316L stainless steel. Dr. Leonard further details, on an element by element basis, that there are insubstantial differences between polymer and metal stents in their "functions, ways and results." For example, both stents employ the same "way" of resisting compressive forces after expansion in the area to be treated by having a material in the stent which increases in rigidity after expansion of the balloon. The insubstantial difference is that the material in a polymer stent is a polymer and the material in the Cordis stents is 316L stainless steel, both of which nonetheless share the physical property of increasing in rigidity after expansion of the balloon.

Therefore, AGR's experts, particularly Dr. Leonard and Dr. Pope, have provided testimony supporting a finding of that all six claim limitations of claim 2 are present in the Cordis stent. They have testified that the Cordis stent and the Rockey sleeve **function** in the same **way**, and/or their differences are insubstantial, because both are small and compact enough to be inserted along with a catheter and a balloon (step one of claim 2) and manipulated into a body vessel (step two of claim 2), after which the balloon is inflated, causing the stent or sleeve, which is made of or supplied with a material that increases in rigidity after the balloon begins to ex-

pand (step four of claim 2), to expand towards the wall of the vessel (step three of claim 2), and the balloon is maintained in an expanded condition until the sleeve or stent is sufficiently rigid (step five of claim 2), and finally the balloon and catheter are removed from the vessel while the stent or sleeve is left in place (step six of claim 2), causing the vessel to remain open (the **result** of both inventions). Dr. Laird, on the other hand, applies the reverse doctrine of equivalents and finds that the two inventions do not function in the same way to achieve substantially the same result because the stainless steel in the Cordis stents increase in rigidity " in an entirely different way" than the material described in the '1,653 Patent. (Laird Expert Report, p. 16-17).

Thus, in accordance with Rule 56(c), Fed. R. Civ. P., there is a genuine issue of material fact precluding summary judgment on the issue of whether the Palmaz stent and the Rockey sleeve function in substantially the same way to achieve substantially the same result, or whether the differences between them are insubstantial, under the doctrine of equivalents.

d. *The Validity of the Rockey '1,653 Patent*

AGR seeks a construction of the '1,653 Patent that would expand the scope of Dr. Rockey's Patent to cover balloon-expandable metal stents, such as the Palmaz and Palmaz-Schatz stents. Cordis responds that if the Rockey Patents were construed to cover balloon-expandable metal stents, then the prior inventive work of Dr. Palmaz would invalidate the '1,653 Patent under 35 U.S.C. § 102 (g). *See Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001) ("[I]f a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent."). Cordis has the burden of proof on the issue of invalidity, and it must present clear and convincing evidence in order to prevail on this

issue. *See, e.g., Magnivision, Inc. v. The Bonneau Co.*, 115 F.3d 956, 958 (Fed. Cir. 1997) ("The presumption [of patent validity] operates by placing the burden of proving invalidity on the person attacking the patent, who must prove invalidity by clear and convincing evidence. ") (citing 35 U.S.C. § 282). The ultimate burden of providing invalidity remains with the challenger throughout the litigation. *Id.*

Cordis has not sought a summary judgment on the invalidity defense, but it has raised the issue in its briefs in support of summary judgment. The evidence presented in connection with summary judgment, including the expert testimony, raises genuine issues of material fact for trial regarding the validity of the Rockey Patents, including but not limited to: (1) the date that Dr. Palmaz conceived of and reduced to practice, according to the provisions of 35 U.S.C. § 102(g), the balloon-expandable metal stents sold by Cordis; (2) the date that Dr. Rockey conceived of and reduced to practice, according to the provisions of 35 U.S.C. § 102(g), the device claimed in the '1,653 Patent; and (3) the "priority date" that applies to the claims of Dr. Rockey's '1,653 Patent corresponding to the proper application filing date for the Patent under 35 U.S.C §§ 112, 120, including the related issue of whether each of the claims in the '1,653 Patent were disclosed in the June 2, 1978 '010 Application, which is the earlier filing date that AGR seeks to apply. In other words, even assuming that Dr. Palmaz's stents contain all of the claim limitations of claim 2 of the Rockey '1,653 Patent, there are remaining factual disputes regarding who invented the subject matter, *i.e.*, balloon-expandable metal stents, first. *See, e.g., T & T Geotechnical, Inc. v. Union Pacific Res. Co.*, 944 F. Supp. 1317, 1320-21 (N. D. Tex. 1996) (denying summary judgment because evidence raised genuine issues of material fact on issue of patent validity); *P.A.T. Co. v. Ultrak, Inc.*, 948 F. Supp. 1506, 1515-16 (D. Kan. 1996); *Acoustiflex Corp. v. Owens-Corning Fiberglas Corp.*, 572 F. Supp. 936, 937 (N.D. Ill. 1983) ("[A] patent case is not ripe for summary

judgment on the issues of validity or enforceability where the technical aspects are not readily comprehensible by one unskilled in the art, where the record is inadequate to decide the issue, where there is a need for expert testimony, where the expert testimony submitted is conflicting, or where there is some other genuine issue of credibility on a motion for summary judgment."). *And see H.B. Fuller Co. v. National Starch & Chem. Corp.*, 595 F. Supp. 622, 624 (D. Del. 1984) (finding issues of fact precluding summary judgment regarding whether patent allegedly infringed could be credited with earlier filing date of a parent application).

e. *The Statute of Limitations*

This action was commenced on July 1, 2002. Cordis argues that all of AGR's claims are barred under the Florida five-year statute of limitations for breach of contract actions, to the extent that AGR seeks damages for sales of Cordis' stents prior to July 1, 1997. The parties agree that the five-year statute of limitations in Section 95.11(b)(2) of the Florida Statutes applies here.

Under Florida law, where a contract requires payments in installments, the applicable statute of limitations ordinarily starts to run on the date each payment becomes due. *See, e.g., Isaacs v. Deutsch*, 80 So.2d 657, 660 (Fla. 1955); *Holiday Furniture Factory Outlet Corp. v. State of Florida, Dep't of Corr.*, 852 So.2d 926, 928 (Fla. 1st DCA 2003); *Bishop v. State of Florida, Div. of Retirement*, 413 So.2d 776, 778 (Fla. 1st DCA 1982); *Central Home Trust Co. of Elizabeth v. Lippincott*, 392 So.2d 931, 933 (Fla. 5th DCA 1980). A contract that contemplates payments to be made at different times is analogous to an installment payment contract. *Hannett v. Bryan*, 640 So-2d 203, 204 (Fla. 4th DCA 1994). Where the installment contract contains an optional acceleration clause, the statute of limitations may commence running earlier on payments not yet due if the holder exercises its right to accelerate the total debt because of default. *Central Home*, 391

So.2d at 933. In that situation, "the entire debt does not become due on the mere default of payment; rather, it becomes due when the creditor takes affirmative action to alert the debtor that he has exercised his option to accelerate." *Greene v. Bursey*, 733 So.2d 1111, 1115 (Fla. 4th DCA 1999).[15]

In cases analogous to this one in which a patent licensor has brought action against a licensee for breach of contract in connection with a licensee's failure to pay royalties under a license agreement, courts have found that because the royalty payments were due at different times, a separate and distinct cause of action accrued for each payment as it became due, and the statute of limitations started to run on each payment due date. *See Moore v. Medtronic, Inc.*, 2001 WL 1636248, *3 (D. Minn. 2001) (applying Minnesota law and finding that royalties that accrued, *i.e.*, that were due, prior to six years (the applicable statute of limitations period) before filing of complaint were barred); *Refac Financial Corp v. Patlex Corp.*, 912 F. Supp. 159, 162-63 (E.D. Pa. 1996) (applying Pennsylvania law); *H.M. Chase Corp. v. Idaho Potato Processors, Inc.*, 529 P.2d 1270, 1272 (Idaho 1974) (applying Idaho law; license agreement called for installment royalty payments to be paid on the tenth day of each month for the production of the preceding month). In *Refac*, the court rejected the argument that the license agreement was a continuing contract such that the statute of limitations did not begin to run until the contract was terminated, finding that the alleged breach (royalty deductions taken by patent licensee) had admittedly occurred, so that the statute had begun to run as to each deduction when taken. *Refac*, 912 F. Supp. at 162-63.

Assuming the jury finds Cordis' stents are covered by the Rockey Patents and that, therefore, the License Agreement required Cordis to make royalty payments to AGR, Cordis is correct that each royalty payment is a severable portion of the contract which starts the statute of limitations running. Cordis

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[15] The License Agreement does not contain such an acceleration clause.

and AGR agree that royalty payments that became due on or after July 1, 1997 are not time-barred. This would include royalties on sales made before July 1, 1997, as long as those royalties became due on or after July 1, 1997. However, AGR is barred by the five-year statute of limitations from seeking damages for royalties that became due prior to July 1, 1997.[16]

The undersigned notes that, under the License Agreement, royalties are not due every three months, but every three months following Cordis' first $20 million in sales of products covered by the Rockey Patents, defined in the License Agreement as the "Royalty Date." There are genuine issues of fact as to the exact date Cordis achieved $20 million in sales of stents covered by Rockey Patents (if this even occurred), and the subsequent dates that each royalty payment became due.

3. Breach of Duty to Exploit (Count II)

Count II alleges that the exclusive licensing provision of the License Agreement subjects Cordis to an implied duty and obligation to use its "best efforts" to perform under the contract, and despite that obligation, Cordis has failed to properly commercialize the inventions disclosed and claimed in the Rockey Patents. In other words, AGR alleges that Cordis breached an "implied duty" by not developing **some** product that **would** practice the Rockey Patents and therefore require the payment of royalties. Cordis argues that AGR is essentially trying to rewrite the License Agreement because the

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[16] The Court rejects AGR's argument that the statute of limitations has not begun to run under the continuing breach doctrine, which provides that on a contract requiring serial performance by the parties, accrual of a breach of contract cause of action commences upon the occurrence of the last breach or the termination of the contract. AGR maintains that the License Agreement is still in force and has not been terminated. The "continuing breach" doctrine that AGR relies on only applies to contracts calling for a single, continuous performance; it does not apply to contracts like the License Agreement that call for performance (*i.e.*, royalty payments) in separate and distinct installments.

Agreement does not contain any provision obligating Cordis to try to develop a Licensed Product.

There is no explicit "best efforts" clause in the License Agreement. Cordis cites to Florida law holding that parties are not entitled to alter or add negotiated obligations defined in contracts by reading implied duties into an agreement. Under Florida law, the governing law under the License Agreement, an action for breach of an implied contractual duty cannot be maintained "in the absence of breach of an express contractual provision," and there is no express contractual provision obligating Cordis to develop a royalty-generating product. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1318 (11th Cir. 1999). While AGR refers to representations allegedly made by Cordis during negotiations prior to execution of the Agreement, those alleged representations regarding anticipated income from commercialization of the Rockey technology, etc., may not be considered because they are barred by the merger clause in the License Agreement.

Furthermore, where a license agreement contains a merger or integration clause and requires a substantial advance royalty payment, courts have consistently refused to read an "implied duty to exploit" into the agreement, and have granted or affirmed summary judgment dismissing claims alleging breach of an "implied duty to exploit." *See, e.g., Permanence Corp. v. Kennametal, Inc.*, 908 F.2d 98 (6th Cir. 1990) (finding no implied obligation on the part of licensee under patent license agreement to use its best efforts to market product embodying patent, so as to maximize licensor's royalty income; licensee had paid licensor a $150,000 fee and a $100,000 advance against royalties, thus providing consideration for agreement other than its best efforts undertaking, and agreement contained merger clause); *Beraha v. Baxter Health Care Corp.*, 956 F.2d 1436, 1442 (7th Cir. 1992) (court would not provide by implication a "best efforts" clause in exclusive patent license agreement where licensor negotiated increase in advance royalties and royalty payments, and agreement

contained merger clause).[17] The substantial advance royalty payment of $2 million paid by Cordis to AGR provided AGR with bargained-for consideration. (Cordis Statement of Facts, p. 2; AGR's Response to Cordis' Statement of Facts, p. 10 (AGR admits that Cordis made a $2 million advance royalty payment to AGR)). Paragraph 3.2 of the License Agreement provides that the $2 million payment "shall be considered pre-paid royalties for the Advance Sales."

It is unnecessary to imply a duty to use best efforts to exploit technology that arises from a patent license agreement like the License Agreement at issue because (1) AGR refers to no express provision of contract the on which it relies - no "best efforts" clause; and (2) there was a substantial advance payment of royalties to AGR. Thus, summary judgment is appropriate on this Count.

4. Breach of Duty of Good Faith and Fair Dealing (Count III)

AGR sues Cordis in Count III for breach of the implied duty of good faith and fair dealing in connection with the License Agreement as a result of Cordis' failure to extend the life of the Rockey Patents. The express provision of the License Agreement that concerns extensions of the term of the Rockey Patents states that "Cordis **may** attempt to obtain a term extension for the Patents if Cordis determines that the

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[17] *See also HML Corp. v. General Foods Corp.*, 365 F.2d 77 (3d. Cir. 1966) (finding no best efforts obligation where there was substantial cash payment required in exclusive licensing contract); *Triple Point Tech. Inc. v. D.N.L. Risk Mgmt., Inc.*, 2000 WL 1236227, *34 (D.N.J. 2000); *Para-Data Computer Networks, Inc. v. Telebit Corp.*, 830 F. Supp. 1001, 1006 (E.D. Mich. 1993) (finding no duty to use best efforts implied in exclusive licensing contract that included $1 million up-front payment and additional $1 million in prepaid royalties); *Kardios Systems Corp. v. The Perkin-Elmer Corp.*, 645 F. Supp. 506,509 (D. Md. 1986) (finding no best effort obligation due to up-front payments of almost $200,000); *Vacuum Concrete Corp. v. American Mach. & Foundry Co.*, 321 F. Supp. 771 (S.D.N.Y. 1971).

likely term extension will result in an additional amount of Running Royalties which exceeds the reasonable cost of obtaining such extension." (License Agreement, § 14.9) (emphasis added). This language gives Cordis substantial, if not complete, discretion in deciding whether to seek a term extension.

As Cordis points out, in attempting to show that Cordis has unreasonably exercised its discretion and thereby breached the implied covenant of good faith and fair dealing, AGR has a heavy burden. Admittedly, the implied covenant of good faith and fair dealing is a part of every contract under Florida law. *Ernie Haire Ford, Inc. v. Motor Co.*, 260 F.3d 1285, 1291 (11th Cir. 2001) (citing *Burger King*, 169 F.3d at 1315). The implied covenant cannot override an express contractual term, *id.* (citing *Ins. Concepts & Design, Inc. v. Healthplan Servs., Inc.*, 785 So.2d 1232, 1234 (Fla. 4th DCA 2001)), but "[w]ith the implied covenant, one party cannot **capriciously** exercise discretion accorded it under a contract so as to thwart the contracting parties' **reasonable expectations**." *Id.* (emphasis added) (citing *Sepe v. City of Safety Harbor*, 761 So.2d 1182, 1185 (Fla. 2d DCA 2000) (holding that, even where one party has "sole discretion" under a contract, that party, in exercising its discretion, must act in good faith and in accordance with the contracting parties' expectations); *Cox v. CSX Intermodal, Inc.*, 732 So.2d 1092, 1097-98 (Fla. 1st DCA 1999) (same)). AGR's burden is to show that no reasonable party would have made the same discretionary decision Cordis made. *See, e.g., Sepe*, 761 So.2d at 1185.

In applying the foregoing principles, courts in Florida and in this Circuit have focused on whether the discretionary decision frustrated the central purpose of the contract. Notwithstanding the broad discretion afforded in the underlying contract, one Florida appellate court reversed a summary judgment in favor of the defendant, finding that there were issues of fact as to whether the manner in which the defendant exercised its discretion violated the implied duty of good faith,

fair dealing and commercial reasonableness. *Cox*, 732 So. 2d at 1097-98. The Eleventh Circuit reviewed the *Cox* decision and noted that "[t]he central purpose of the contract in *Cox* was the hauling of freight. By failing to assign freight [the discretionary act at issue], CSX frustrated that purpose and the reasonable expectation of the parties." *Ford*, 260 F.3d at 1292. The Eleventh Circuit then proceeded to distinguish the facts in *Ford* from the facts in *Cox* as follows:

> Here, however, the central purpose of the Dealership Agreement was to sell cars, not to relocate the dealership. In disapproving the relocation, Appellee did not preclude Appellants from selling cars. Instead, based on 'its best judgment,' Appellee forbid [sic] the relocation of the dealership to a site where, granted, Appellants would have financially benefitted. Although Appellee's decision was not in Appellants' best interests, it was neither capricious nor in contravention of the parties' reasonable expectations.

Id. at 1292; *see also Burger King Corp. v. Ashland Equities, Inc.*, 217 F.Supp.2d 1266, 1275-77 (S.D. Fla. 2002) (granting summary judgment in favor of franchisor on a claim for breach of the covenant of good faith and fair dealing; holding that franchisor's decision not to approve a franchise sale by the franchisees, which was within the franchisor's complete discretion, did not violate the implied covenant because the central purpose of the franchise agreement was the sale of the franchisor's products, not the sale or transfer of restaurants, and the franchisor's decision was not capricious as the prospective purchaser recommended by franchisees did not satisfy the managerial and financial requirements set forth in the agreement).

Here, Cordis' decision not to extend the term of the Rockey Patents is inextricably intertwined with the central purpose of the License Agreement, *i.e.*, providing Cordis with an exclusive license to manufacture, use and sell the products

covered by the Rockey Patents in exchange for Cordis' payment of royalties. AGR alleges that "[s]uch an extension would have resulted in a longer period of time during which Cordis would be obligated to continue to pay the Running Royalties." AGR's assertion is supported by paragraph 7.1 of the License Agreement, which provides that "[u]nless sooner terminated . . ., the term of this Agreement shall be to the end of the term for the last patent to expire of any of the Patents." The determination of whether Cordis is obligated to pay royalties on the accused products is one that will be made by a jury in resolving Count I; and, it appears, assuming *arguendo* that Cordis is obligated to pay royalties on the products at issue, that an extension of the term of the Rockey Patents would have a direct impact on the rights of the parties under the License Agreement.

However, the evidence in the record supports Cordis' assertion that it could not have obtained an extension of the Rockey '1,653 Patent under 35 U.S.C. § 156, and therefore, Cordis' decision not to seek an extension of the Rockey Patent was neither capricious nor in contravention of the reasonable expectation of the parties. Only the first product approved by the "FDA" and covered by the '1,653 Patent (which AGR contends was the Palmaz balloon-expandable stent that received the required approval in 1991), could have been used to obtain an extension,[18] and that approval was the basis for a patent extension of the Palmaz '3,665 Patent in May, 1993. (Reply Appendix in Support of Cordis' Motion for Summary Judgment, Exh. 57 & 58). Only a single patent is entitled to an extension based on an approved product, and an application for an extension must be filed within sixty (60)

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[18] Title 36, Section 156(a)(5), United States Code, provides that the term of a patent shall be extended from the original expiration date of the patent if "the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. § 156(a)(5)(A).

days of approval. 35 U.S.C. §§ 156(c)(4), (d)(1). Because the Palmaz Patent had already been extended, and more than 60 days had passed between the time of approval by the FDA for the Palmaz product (1991) and the License Agreement (1995) and Cordis' merger with J & J (1996), the record reflects that Cordis could not have legally obtained an extension of the Rockey '1,653 Patent. Under the circumstances, it cannot be said that no reasonable party would have made the same decision Cordis made. Accordingly, summary judgment is also appropriate on Count III.

IV. CONCLUSION

For all the foregoing reasons, it is

ORDERED AND ADJUDGED as follows:

1. AGR's Motion *in Limine* to Preclude Evidence Regarding the Validity of the Rockey Patents **(D.E. 102)** is **DENIED.**

2. AGR's Motion *in Limine* to Preclude Uncorroborated Inventor Testimony **(D.E.103)** is **DENIED.**

3. AGR's Motion *in Limine* to Preclude the Expert Testimony of Dr. Campbell Laird and Dr. Joseph Puma **(D.E. 104)** is **DENIED.**

4. AGR's Motion *in Limine* to Preclude Undisclosed Opinion Testimony **(D.E. 105)** is **GRANTED.**

5. AGR's Motion *in Limine* to Preclude Evidence Concerning the Development of the Accused Products and Corresponding Patent Protection **(D.E. 106)** is **DENIED.**

6. Cordis' Motion *in Limine* to Exclude Parol Evidence **(D.E. 108)** is **GRANTED.**

7. Cordis' Motion *in Limine* to Exclude Arguments by AGR that Cordis is Obligated to Pay Royalties on

Products that Practice the Rockey Patents "In Whole Or In Part" **(D.E. 108)** is **GRANTED**.

8. Cordis' Motion *in Limine* to Exclude or Limit the Testimony of AGR's Patent Law Experts **(D.E. 108)** is **GRANTED** in part.

9. Cordis' Motion *in Limine* to Exclude the Testimony of AGR's Experts on Infringement Under the Doctrine of Equivalents **(D.E. 108)** is **DENIED**.

10. Cordis' Motion *in Limine* to Exclude Certain Testimony by George Widas and Edward F. Leonard Under *Daubert* **(D.E. 108)** is **DENIED**.

11. Cordis' Cross-Motion *in Limine* to Preclude AGR from Relying on a Priority Date Earlier than February 19, 1985for Claim 2 of the '1,653 Patent **(D.E. 121)** is **DENIED**.

12. Cordis' Motion to Strike the Supplemental Report of Edward F. Leonard **(D.E. 150)** is **DENIED**.

13. Cordis' Motion for Summary Judgment **(D.E 45)** is **GRANTED** in part. Summary judgment is hereby **ENTERED** in favor of Cordis, and against AGR, on Counts II and III.

14. Cordis' Motion for Construction of Terms in the Claims of the Rockey '1,653 Patent **(D.E. 107)** is **GRANTED** in part.

DONE AND ORDERED in Chambers at Miami, Miami-Dade County, Florida, this 11 day of March, 2004.

s/ Cecilia M Altonaga
CECILIA M. ALTONAGA
UNITED STATES DISTRICT JUDGE
Copies furnished to:

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APPENDIX D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

CASE NO.02-22555-CIV-ALTONAGA/Bandstra

ARLAINE & GINA ROCKEY, INC.,

Plaintiff,

vs.

CORDIS CORPORATION,

Defendant.

_____/

ORDER ON PENDING MOTIONS

THIS CAUSE is before the Court on the following pending motions: Defendant, Cordis Corporation's ("Cordis['s]") Application to Preclude Certain Evidence [D.E. 190]; Cordis' Renewed Motion for Summary Judgment [D.E. 198]; and Plaintiff, Arlaine & Gina Rockey, Inc.'s ("Rockey['s]") Motion for Reconsideration [D.E. 206]. The Court has carefully considered the parties' written submissions, oral arguments presented, the record, and applicable law.

A. Rockey's Motion for Reconsideration

The undersigned will attempt not to repeat that which has already been decided in this case. To that extent, and because it is relevant and necessary for the resolution to the foregoing motions, the Court's Amended Order on Pending Motions [D.E. 189] is incorporated herein by reference. Suffice it to say, as the parties already well know, that in the Amended Order [D.E. 189] of March 11, 2004, the Court agreed with

and substantially adopted Cordis' proposed claim construction.

> In particular, the Amended Order provides the following, critical claim construction:
>
> [T]he claim construction of the phrase "providing in the sleeve a material" is: *to supply in the sleeve a material that is separate and distinct from the sleeve itself.*
>
> * * *
>
> [T]he phrase "increases in rigidity after expansion of the balloon" requires that *the material added to the sleeve* during the procedure increases in rigidity after the balloon begins to expand.

(Amended Order, [D.E. 189] pp. 72, 76)(italics in original).

Rockey's Motion for Reconsideration [D.E. 206], as well as Rockey's reply memorandum and numerous filings of supplemental authority, explain why in Rockey's view, the Court's Amended Order is incorrect, and the Court's original January 5, 2004 Order on Pending Motions [D.E. 159] generally[1] got it right. Rockey would have the Court restore the original claim construction of the "providing in" element, *i.e.*, *to make available as apart or property of the sleeve itself, or to supply into the sleeve, a material.* After yet another painstaking and thorough review of claim 2, the intrinsic and extrinsic evidence, the specifications, the embodiments, the parties' arguments, and applicable law, the undersigned does not find the Amended Order [D.E. 189] to contain "manifest errors of law or fact," *See, e.g., Burger King Corp. v. Ashland Equities, Inc.*, 181 F.Supp.2d 1366, 1369 (S.D. Fla. 2002)

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[1] The undersigned is aware that while Rockey seeks to have the Amended Order further amended to take the parties back to the status that existed upon the entry of the original, January 5, 2004 Order [D.E. 159], Rockey nevertheless also finds fault with the Court's construction, in the January 5, 2004 Order, of the term "sleeve."

(standard on motion for reconsideration), such that reconsideration should be granted and the original claim construction of the January 5, 2004 Order [D.E. 159] be re-adopted. Indeed, careful thought to the very same issues raised in Rockey's Motion for Reconsideration was given before the Amended Order was entered following Cordis' earlier Motion for Reconsideration [D.E. 165].

B. Cordis' Renewed Motion for Summary Judgment

Given the claim construction as detailed in the Amended Order, Cordis filed its Renewed Motion for Summary Judgment [D.E. 198], insisting that summary judgment is now appropriate as there are no factual issues in dispute for the jury to decide, and as a matter of law, Cordis' stents do not infringe Rockey's patent. The Motion is premised on a lack of literal infringement and lack of infringement under the doctrine of equivalents.

Literal infringement analysis involves two steps: the first is the proper interpretation of the asserted patent claim, *i.e.*, "claim construction," which has already taken place and which is a matter of law to be resolved by the court. *See Markman v. Westview Instr., Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580-81 (Fed. Cir. 1996). The second step, the determination of infringement, is a matter of fact to be resolved by the fact finder. *Southwall Tec'is., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "Literal infringement requires a patentee to prove by a preponderance of the evidence that every limitation of the asserted claim is literally met by the allegedly infringing device." *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1302 (Fed. Cir. 2001). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Where the asserted claim does not literally read on the accused product, infringement under the doctrine of equiva-

lents may exist "if there is not a substantial difference between the limitations of the claim and the accused product." *Id.* at 1251.

As to the appropriate standard of review on the request for summary judgment, Rockey correctly points out in its opposition papers,

> It is at least conceivable that comparison of a properly interpreted claim with a stipulated or uncontested description of an accused device or process would reflect such an absence of material fact issue[s] as to warrant summary judgment of infringement or noninfringement. Because infringement itself is a fact issue, however, a motion for summary judgment of infringement should be approached with a care apportioned to the likelihood of its being inappropriate.

D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1573 (Fed. Cir. 1986).

Approaching the Renewed Motion for Summary Judgment with such care, the Court observes that Cordis presents the following as undisputed material facts. First, as noted by the Court in the Amended Order, the Cordis stents are made of a single material, medical grade stainless steel, *i.e.*, 316L stainless steel. Cordis does not provide a material in the stent that is separate and distinct from the stent itself, and physicians do not provide in Cordis' balloon expandable stents a material that is separate and distinct from the stents themselves. Second, Cordis relies on Rockey's admission as contained in its Rule 7.5 Statement, that Cordis does not provide a material in its balloon expandable stents other than the stent itself. According to Cordis, because the claim construction of the Amended Order finds that in the Rockey patent, a material separate and distinct from the sleeve itself must be added to the sleeve, an increase in the rigidity of a material that is contained in the sleeve or that is a part of the sleeve itself, as is

the case with Cordis' stents, is no longer sufficient to satisfy the construction, and infringement has not been shown.

Rockey insists the following disputed material facts require submission of the case to a jury on both the questions of literal infringement as well as infringement under the doctrine of equivalents. First, Rockey's experts have provided opinion testimony that the accused device meets the "providing in" limitation. More particularly, work hardened 316L stainless steel is not in the sleeve when originally manufactured but is in portions of the sleeve after expansion of the balloon begins, and therefore, such qualifies as the "additional" material. Second, Rockey maintains that Cordis is estopped from arguing that the introduction of pressurized fluid, such as with Cordis' product, is not the supplying of a separate material sufficient to meet the "providing in" claim limitation as defined in the Amended Order. Specifically, in its earlier Motion for Reconsideration, Cordis acknowledged that once it reached the area to be treated, "a 'pressurized fluid' - a material that is separate from the sleeve unit - is provided in the filament(s) to expand the sleeve unit 10 from its folded condition ... to an expanded condition." (Cordis Mot. for Recons. at 3). According to Rockey, Cordis cannot now take the position that the introduction of pressurized fluid into the sleeve does not meet the "providing in" claim limitation.

It is appropriate, then, to carefully examine the record evidence Rockey maintains creates disputed factual issues. Rockey relies heavily on opinions furnished by its expert and materials scientist, Dr. David Pope. Dr. Pope opines in part as follows:

> 4. To the extent necessary, this is to set forth my opinions regarding infringement of Claim 2 of the '1,653 Patent utilizing the amended claim term definitions for the element, "providing in the sleeve a material which increases in rigidity upon expansion of said balloon," which have recently been provided by the Court.

* * *

7. Set forth below is the language of Claim 2 of the '1,653 Patent. . . . Claim 2 provides:

A method of treating an area of body vessel, comprising the steps of:

(a) introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel remote from the area to be treated;

(b) manipulating the catheter axially along the vessel at a point to cause the balloon and sleeve to enter the area to be treated;

(c) inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel;

(d) **providing in the sleeve** a **material** which **increases** in **rigidity after expansion** of said **balloon**;

* * *

8. My opinion is limited to that aspect of Claim 2 which contains the language "providing in the sleeve a material which increases in rigidity."

* * *

10. The accused Cordis product at issue in this litigation is a metal stent made from annealed 316L stainless steel which is ***not*** cold worked 316L stainless steel.

11. . . . While the cold worked steel and the annealed steel have the same composition, they have different structures. These different structures result in different properties such that, to a material scientist, the materials are separate and distinct...

22. The portion of the annealed 316L stainless steel that is changed into rigid cold worked 316L stainless steel constitutes no more than 10% of the total amount of steel. The remaining 90% of the stent is made up of annealed stainless steel. Utilizing the court's definition of sleeve, this separate and distinct annealed 316L stainless steel, which comprises approximately 90% of the stent's structure, performs the required function of providing support, increasing the size of the lumen, and isolating material normally flowing into the vessel from direct contact with the interior surface of the vessel. The remaining 10% of the stent, which comprises cold worked 316L stainless steel in very specific locations, performs the required function of increasing the stent's rigidity after the expansion of the balloon.

23. The increase in rigidity takes place as a result of the addition, through deformation, of work hardened 316L stainless steel to the sleeve. This work hardened 316L stainless steel is a separate and distinct material from the annealed 316L stainless steel.

24. Based upon these definitions for the indicated terms, it is my opinion that the fourth element of Claim 2 of the '1,653 Patent is found in the accused Cordis stents. It is my opinion that the accused devices provide in the sleeve a material, which has been defined as to supply in the sleeve a material (*i.e.*, a substance or substances of which a thing is made or composed) that is separate and distinct from the sleeve itself.

* * *

27. The method by which the separate and distinct material (cold worked 316L stainless steel) is supplied in the Cordis sleeve is through the mechanical process of cold working some of the portions of the sleeve (initially structured as annealed 316L stainless steel) where the struts intersect or bend so that they are restructured into

a new, distinct, separate and more rigid material (cold worked 316L stainless steel).

28. Further, utilizing the Court's requirement that the material added to the sleeve during the procedure increase in rigidity after the balloon begins to expand, the cold worked 316L stainless steel meets this limitation.

* * *

30. A method by which one supplies in the sleeve a material that is separate and distinct from the sleeve itself by way of physically adding to the sleeve new molecules that increase in rigidity after the balloon begins to expand, functions in substantially the same way to achieve substantially the same result as the method used by Cordis by which one supplies in their sleeve (or stent) a material that is separate and distinct from the sleeve itself by way of the mechanical process of cold working some of the existing material in the sleeve (consisting of atoms in a certain arrangement) so that they are restructured into a new, distinct and separate material which increases in rigidity after the balloon beings to expand.

* * *

(Plaintiff's Response to Renewed Mot. S.J. at Ex. A) (emphasis in original).

Rockey also relies on the opinions of Dr. Edward Leonard, a biomedical engineer. Dr. Leonard generally agrees with and echoes Dr. Pope's opinions, and adds:

24. The accused device functions in the exact same manner. Adding the pressurized fluid through the trailing filaments of the accused device (as discussed in the '1,653 Patent's Specification), causes the unit to expand and to stiffen. This stiffening (increase in rigidity) takes place as a direct result of the addition of the pressurized fluid ("a separate material") which directly causes an in-

> crease in rigidity through the increase in the pressure of the fluid in an enclosed space as well as: (1) the cold working of the 316L stainless steel; (2) the reorientation of the struts; and, (3) the invagination of the struts into the vessel wall - all of which are directly caused by the introduction of the pressurized fluid.

(*Id.* at Ex. B).

In addition to the argument that factual issues preclude a summary judgment, Rockey relies on Cordis' own statements contained in Cordis' earlier Motion for Reconsideration [D.E. 165] to argue that Cordis should be estopped from insisting that the accused products' introduction of "pressurized" fluid through the trailing filament into the balloon does not meet the Court's definition of the "providing in" limitation, *i.e.*, *supplying in the sleeve a material separate and distinct from the sleeve itself.* In discussing the Fig. 1-7 embodiment of the '1,653 patent, Cordis previously noted:

> Contrary to the Court's finding in the January 5 Order, every embodiment described in the '1,653 patent has a separate material that is added into the sleeve unit to increase its rigidity and enable it to function as a "sleeve." The Fig. 1-7 embodiment is no exception.
>
> * * *
>
> Initially, when the Fig. 1-7 sleeve unit is introduced into the patient's body, it is "folded on itself accordion fashion to reduce its length and diameter." ... Once it reaches the stomach, a "pressurized fluid" – ***a material that is separate*** **from** ***the sleeve unit*** - is provided in the filaments to expand the sleeve unit 10 from its folded condition ... to an expanded condition...
>
> * * *
>
> When the sleeve unit 10 is in the desired position, a "pressurized fluid" ***-again, a material that is separate***

> **from *the sleeve unit itself*** - is provided in the ring balloons, which are part of sleeve unit 10 .

(emphasis in original).

The foregoing summarized opinions, combined with Cordis' statements taken from its earlier Motion for Reconsideration [D.E. 165], do not create a factual issue for submission to a jury, under either a theory of literal infringement or infringement under the doctrine of equivalents. It is undisputed that Cordis' stents are made of 316L stainless steel before they are expanded and they continue to be made of 316L stainless steel after they are expanded. Dr. Pope admits that annealed 316L stainless steel and cold worked 316L stainless steel "have the same composition;" (Pl. Resp. to Ren. Mot. S.J. at Ex. A, ¶14); "no new atoms are being added to the stent" when it is cold worked. (Cordis' Reply Br., Ex. 3 at 36:11-19). A change in the characteristics of the 316L stainless steel contained in the Cordis stent is not the addition of a material "*separate and distinct from the [stent] itself.*" (Am. Order, [D.E. 189] p. 72).

Moreover, Dr. Pope admitted in his deposition that all of the stainless steel in Cordis' stents is part of the stent itself. (Cordis' Reply Br., Ex. 4 at 48:21 - 49:3). None of that material is separate and distinct from the accused product - the stent itself. Dr. Leonard also admitted that Cordis' stents would not infringe under the Court's claim construction:

> Q. If the Court interprets this as requiring a sleeve to exist, and then material to be added to that sleeve, and that material increases in rigidity, does - do the Cordis products, do that - perform that limitation?
>
> * * *
>
> A. No, they don't.

(Cordis' Ren. Mot., Ex. A. at 140:23 - 141:5).

In its Rule 7.5 Statement in opposition to Cordis' original Motion for Summary Judgment, Rockey also "admitted that Cordis does not provide a material in its balloon expandable stents other than the stent itself." (D.E. 66 at 6). Rockey now explains that it is the "end user (physician), not Cordis" who performs the "providing in" step, when the balloon on which the stent is mounted is inflated, and thereby "causes the cold working that supplies the new material to the sleeve." (Rockey Resp. to Ren. Mot. S.J. at 13). However, this new position is in direct contradiction to Dr. Pope's earlier testimony of July 11, 2003:

> Q. . . .[N]ow just to make sure that I have it, and tell me if I've got it right, the steps that Cordis does that you think satisfy the "providing in the sleeve" limitation are the stent designer's decision to go and use 316L stainless steel and Cordis' acquisition of stainless steel tubing; is that correct?
>
> A. Yes.
>
> Q. And there is nothing else that anybody else does that in your opinion is part of the "providing in" step?
>
> A. I believe that's correct, yes.

(Cordis' Rep. Br., Ex. 4 at 55:19 - 56:6). Rockey cannot now advance the argument that it is the end user who performs the "providing in" step to create a triable issue.

In sum, the material that Rockey focuses on to oppose the entry of a final summary judgment, the cold worked 316L stainless steel, is part of the stent and is contained in the stent. It is not *separate and distinct from the [stent] itself.* Rockey's position that a separate and distinct material does not need to be physically added to the sleeve is in direct contradiction to the construction as contained in the Court's Amended Order, that the phrase "providing in the sleeve a material" is *to supply in the sleeve a material that is separate and distinct from the sleeve itself* (D.E. 189 at 72).

Furthermore, Rockey misapprehends what material is the one required to "increase in rigidity." The Court previously determined that the phrase "increases in rigidity after expansion of the balloon" requires that *the material added to the sleeve during the procedure increases in rigidity after the balloon begins to expand.* (*Id.* at 76). Rockey would have that condition be satisfied by having the 316L stainless steel of the stent itself be the material which increases in rigidity when the annealed stainless steel changes to cold worked stainless steel. This is a "substantial difference" between the limitations of the claim and of the accused product.

As to the argument premised on judicial estoppel,[2] Rockey picks up on statements previously made by Cordis concerning the Fig. 1-7 embodiment. Those statements are not material to the issue being considered, as claim 2 was not addressed to the "sleeve unit" of Fig. 1-7. Nothing in the claim language suggests that a balloon is part of the claim 2 "sleeve." Nothing in the specification suggests that a balloon is part of the "sleeve" for the Fig. 9 embodiment. Claim 2 is directed to the Fig. 9 embodiment, not the embodiment of Fig. 1-7, and thus Cordis' statements highlighted by Rockey do not operate an estoppel.

Literal infringement has not been shown, and no material factual issues exist to support such a finding. On the question of the doctrine of equivalents, "[a]n element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Searfoss v. Pioneer Cons. Corp.*, , 374 F.3d 1142, 1150 (Fed. Cir. 2004) (quoting *Eagle Comtronics, Inc. v. Arrow Communication Labs., Inc.*, 305 F.3d 1303, 1315 (Fed. Cir. 2002)). In assessing whether the differences are insub-

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[2] The doctrine of judicial estoppel is that a party should not be allowed to gain an advantage by relying on one theory and then seeking an inconsistent advantage by pursuing an incompatible alternate theory. *See Barger v. City of Cartersville, Georgia*, 348 F.3d 1289, 1293-94 (11th Cir. 2003).

stantial, the court should ascertain "whether the accused product performs the same function, in the same way, with the same result." *Id.* (construing "connecting" in a patent for movable truck bed cover systems, and finding "connecting" meant only a direct connection and not an indirect connection because patent referred to "connecting" as synonymous with "attaching").

Here, the accused Cordis stent simply does not perform the same function in the same way as the Rockey patent. The differences between annealed and cold worked 316L stainless steel do not satisfy the Court's construction of the Rockey patent in question. Cordis simply does not provide a material in its balloon expandable stents other than the stent itself. A finding of infringement under the doctrine of equivalents here would vitiate the requirement of a material "*separate and distinct from the sleeve itself*" which is "*added to the sleeve*."

Accordingly, and for the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Application to Preclude Certain Evidence [D.E. 190] is **DENIED** as moot, the Motion for Reconsideration [D.E. 206] is **DENIED**, and the Renewed Motion for Summary Judgment [D.E. 1981 is **GRANTED**. Final judgment shall be entered in favor of Defendant, Cordis and against Plaintiff, Rockey. The Clerk of the Court is instructed to **CLOSE** the case.

DONE AND ORDERED in Chambers at Miami, Miami-Dade County, Florida this 24 day of January, 2005.

s/ Cecilia M. Altonaga
CECILIA M. ALTONAGA
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Magistrate Judge Ted E. Bandstra
Counsel of record

APPENDIX E

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public order.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

Before Michel, Chief Judge, Schall, Circuit Judge, and Gajarsa, Circuit Judge,

A petition for rehearing having been filed by the Appellant,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED,

The mandate of the court will issue on April 18, 2006.

FOR THE COURT,

s/ Jan Horbaly

Jan Horbaly

Clerk

Dated: 04/11/2006

cc: Frederick A. Tecce

William F. Cavanaugh, Jr.

ARLAINE & GINA ROCKEY INC V CORDIS, 2005-1236 (DCT - 02-CV-22555)

APPENDIX F

US PAT 4641653, 1987 WL 541649 (U.S. PTO Utility)

United States Patent

Patent Number: US 4641653

Document Type: Utility

Title: MEDICAL SLEEVE

Issue Date: February 10, 1987 (19870210)

Inventor(s): Rockey, Arthur G. (3438 Sharon Rd., Charlotte, NC 28211)

Application Number: 702828

Application Date: February 19, 1985 (19850219)

Related: Continuation-in-part of Ser. No. 216,989, December 16, 1980 (19801216), Pat. No. 4501264, which is a continuation of Ser. No. 912,010, June 02, 1978 (19780602), now abandoned.

International Class: [4] A61M-029/02

U.S. Class: 128/344; 604/096

Field of Search: 128/001 R; 128/092 C; 128/303 R; 128/030.11; 128/325; 128/334 R; 128/344; 604/096-103; 604/008; 604/175

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Other Publications:

New Products and Processes in *Polymer News,* vol. 7, No. 5, May 1981, p. 219.

Primary Examiner: Rosenbaum, C. Fred

Asst. Examiner: Smith, Jr., Jerome R.

Attorney/Agent/Firm: Pearne, Gordon, McCoy & Granger

ABSTRACT:

A method and article for medical diagnosis and/or treatment of body disorders, comprising a sleeve unit insertable in a natural body vessel to isolate material flowing into the vessel from direct contact with the interior surface of the vessel. When applied to the treatment of obesity, the sleeve is disposed along a zone in the digestive tract to interfere with the digestive or absorptive function of that zone and thereby reduce net caloric intake.

Claims: 2

Patent Pages: 9

Drawing Sheets: 4

This is a continuation-in-part of my copending application Ser. No. 216,989, **filed Dec.** 16, 1980, **now U.S. Pat. No.**

4,501,264 **which is a continuation of prior application Ser. No.** 912,010, **filed June** 2, 1978, **now abandoned.**

BACKGROUND OF THE INVENTION

In the diagnosis and/or treatment of disorders of the body, it is known to physically alter the condition or function of hollow viscera or other internal body vessels. Surgical procedures on such vessels include reconstruction of natural tissue, substitution and bypass techniques with natural or artificial implants. Surgery is recognized as always carrying some degree of risk to the patient, both during its actual performance and in postoperative complications or side effects. These risks, of course, are of major concern when the surgery involves the invasion of the great cavity of the trunk of the human body. This is especially ture in treatment of such viscera as the heart, liver, or intestines, and in particular when such surgery involves these organs themselves.

In surgical treatment of obesity, for example, the abdominal cavity is exposed to allow reconstruction of the digestive tract, in essence, to reduce the internal surface area available for food digestion or absorption of digested substances. The former technique, a gastric bypass, may be accomplished by anastomosing a minor portion of the stomach to the jejunum while leaving the major portion connected to the duodenum. The latter of these techniques, an intestinal bypass, involves the short-circuiting of a majority of the combined lengths of the jejunum and ileum by connecting the first part of the jejunum to the last part of the ileum.

Both of these operations are deemed to involve such high risk to the patient that they are considered only as a lifesaving undertaking for morbidly obese individuals. Beyond statistically significant operative and overall mortality rates, reported complications following the gastric bypass include marginal ulcers and wound infections. The intestinal bypass involves similar mortality rates and, reportedly, a greater number of postoperative complications and side effects.

These include pulmonary emboli, wound infections, gastrointestinal hemorrhage, renal failure, and numerous other disorders. The nature, severity, and frequency of these problems have in fact led to doubts as to the advisability of the techniques for treatment of obesity.

SUMMARY OF THE INVENTION

The invention provides a method and means for isolating the internal walls of hollow viscera or other body vessels from contact with materials, both fluids and solids, occurring naturally, ingested, or otherwise introduced into a body vessel. Isolation of a body vessel, according to the invention, is achieved by positioning and anchoring a sleeve, impervious to materials sought to be isolated within the vessel, in such a manner that the sleeve, at least adjacent its upstream end, is in sealing engagement with the surrounding interior tissue of the vessel. Material otherwise normally flowing into the vessel and being capable of interracting with the vessel to the detriment of the patient's health is thereby contained and rendered ineffectual or on unaffected by the vessel.

An important application of the invention is the nonsurgical treatment of obesity through reduction in the effective natural surface area of the digestive tract. In one disclosed embodiment, a sleeve impervious to both gastric secretions and food substances is disposed within the stomach in a manner which prevents contact between these gastric secretions and food substances. More specifically, the sleeve acts as a liner for at least a portion of the internal stomach area while also providing a conduit for food passing through the stomach. The sleeve, which is capable of establishing a circumferential, substantially fluidtight seal with the walls of the stomach adjacent its upstream end, may be any desired length so that a suitable portion of the internal stomach area is rendered ineffectual in the digestive process. Consequently, the sleeve is operative to limit the efficiency of food absorption in the small intestine.

As disclosed, the sleeve may be introduced into the stomach through the oral cavity and esophagus. In the preferred embodiment, the sleeve is sufficiently flexible to be collapsed into a unit of relatively low bulk for ease of passage through the posterior pharynx and esophagus. Upon reaching a desired position in the stomach, the sleeve is expanded by means carried with the sleeve, including a flexible tube trailing the sleeve. A source of pressurized fluid external of the patient's body is operably connected to the expanding means through this trailing tube to expand the sleeve into sealing engagement with the walls of the stomach. The sleeve may be additionally restrained against further movement along the digestive tract by anchoring the trailing tube or a separate parallel element upstream in the digestive tract.

The tissue isolating function of the disclosed sleeve, in addition to control of the mechanism of digestion, has numerous other applications in diagnosis or treatment of body disorders. For example, the sleeve may be used to chemically and/or physically protect tissue which has been ulcerated, herniated, fissured, or the like from natural body fluids. Ruptured blood vessels or aneurysms may be protected from further damage and allowed to heal by isolating the effect of normal blood pressure from the vessel by containing it within the sleeve.

Stenosis or a sclerotic closing of an artery may be expanded from within by the use of internal compression while still allowing blood to pass through, especially in those individuals whose disease is so far advanced that a graft could not be sutured to the distal portion of the vessel. Still further, where desired, one or more tubes connected to the sleeve may be arranged to provide communication between the annular zone intermediate the protected vessel and the outer surface of the sleeve for introduction of medicines or aspiration of fluids from the zone.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a vessel-insertable medical sleeve unit constructed in accordance with the invention;

FIG. 2 is a fragmentary, cross sectional view on an enlarged scale through the wall of the sleeve unit, taken along the line 2--2 of FIG. 1;

FIG. 2*a* is a fragmentary, cross sectional view similar to FIG. 3, taken along the line 2 suba --2 suba of FIG. 1;

FIG. 3 is a fragmentary, cross sectional view on an enlarged scale, taken along the line 3--3 of FIG. 1 of a trailing filament of the sleeve unit;

FIG. 4 is a schematic illustration of a manner of use of the sleeve to control obesity;

FIG. 5 is a view of the sleeve unit in a compacted condition and contained within a dilator shell for installation;

FIG. 6 is a view of the sleeve unit depicting an intermediate configuration in a progressive sequence of expansion from the condition of FIG. 4;

FIG. 7 is a view of the sleeve progressed in its transition from FIG. 5 through FIG. 6 to a fully expanded configuration essentially corresponding to FIG. 4;

FIG. 8 is a schematic view of a second embodiment of the sleeve of the invention employed within an aorta; and

FIG. 9 is a sectional view in a longitudinal plane of a ring balloon and associated implantable sleeve disposed in a blood vessel of an animal body.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and in particular to FIG. 1, there is shown a sleeve unit 10 in the form of a cylindrical, tubular sheath 11 and one or more inflator ring balloons 12-14. The sheath 11 in the illustrated example if a flexible

membrane of nontoxic material impervious and chemically resistant to body fluids which it is expected to encounter. The sheath material is selected from a variety of known plastic and/or elastomeric substances. The sheath 11 may be extruded, rolled, or otherwise formed, as desired, into a tube with or without a longitudinal seam or seams.

The inflator ring balloons 12-14 as indicated in FIG. 1 are flexible, hollow, torroid-like elements spaced axially along the interior of the sheath 11. As indicated, the rings 12 and 14 are adjacent opposite ends 16 and 17 of the sheath 11. The ring balloons 12-14 may be formed of a material the same as or like that of the sheath 11, and are either integrally formed thereon or are bonded thereto by heat, adhesive, solvent or like means. While the sheath 11 is illustrated as a cylinder, it will be understood that it may take other configurations, such as a frustum or a sphere truncated adjacent opposite poles, or a tubular elbow of constant or varying diameter. The sleeve unit 10 includes at least one, and preferably two, trailing hollow filaments 20,21 connected thereto by bonding or other suitable means. These filaments 20,21 may be made of the same or similar material as the sheath 11. In the illustrated case, each of the filaments 20-21 includes a central lumen 22 and an auxiliary lumen 23. When desired or necessary, additional lumens may be disposed in the wall of each filament 20-21. Ideally, one of the filaments 20 has its central lumen 22 in fluid communication with an upstream one 12 of the ring balloons, while the other filament 21 has its central lumen 22 in fluid communication with the remaining ring balloons 13 and 14.

As suggested in FIG. 3, longitudinally spaced, generally radial passages 26 provide communication from the auxiliary lumens 23 of each filament 20, 21 through the adjacent wall of the sheath 11 to points external of the sleeve unit 10. The exterior surface of the filaments 20,21 and internal surface of the sheath 11 are sealed to one another by suitable means, such as bonding or the like, at their points of tangency so that

fluids in the auxiliary lumens cannot escape into the interior, designated 27, of the sheath 11 at the radial passages or apertures 26.

The sleeve unit 10 is implanted in a body vessel in order to isolate the walls of such vessel from fluids normally flowing into it. FIG. 4 illustrates a manner of use of the sleeve unit 10 to isolate the internal surface area or lumen, designated 31, of a human stomach 32 and its secretions from food substances passing through it. The sleeve unit 10 is implanted in the stomach 32 in a nonsurgical manner by passing it through an oral cavity 33, pharynx 34, and esophagus 35. To facilitate introduction of the sleeve unit 10 into the stomach 32, the sleeve unit is folded on itself accordion fashion to reduce its length and diameter. In its folded or compacted state, the sleeve unit 10 is contained within a dilator shell or cup 37 (FIGS. 5 and 6). The dilator shell 37 has a rounded profile for ease of passage through the natural lumen of the digestive tract, generally indicated at 39 (FIG. 4). The dilator shell 37 carrying the collapsed sleeve unit 10 is inserted through the epiglotis, whereupon natural swallowing action allows it to be readily advanced into the stomach 32.

Upon reaching the stomach 32, one or both of the central lumens 22 of the filaments 20,21 are connected to a source of pressurized fluid, such as air, ordinarily external of the oral cavity 33. Lower sections of the filaments 20, 21 longitudinally associated with the sheath 11 develop forces upon pressurization, tending to unfold themselves along with the sheath. FIG. 6 depicts this action, wherein the dilator shell 37 is released from the sleeve unit 10 and allowed to pass through the lower portion of the digestive tract 39. The sleeve unit 10 in a continuous sequence of movement expands from the intermediate position of FIG. 6 to that of FIG. 7.

The final position of the sleeve unit 10 in the stomach 32 may be adjusted by pumping fluid through the auxiliary lumens 23 in such a manner that it issues from the passages 26

as a jet developing a reaction force to shift the adjacent area of the sleeve unit in one direction or another, depending on the orientation of the passages. These passages 26 may be provided with either an axial or tangential component in their orientation with respect to the axial direction of the sleeve to cause corresponding axial or turning movement of the sleeve. Preferably, the sleeve unit 10, including the filaments 20, 21 and ring balloons 12-14, is provided with sufficient radiopaque material to permit external observation of its position and configuration. When the position of the sleeve unit 10 is satisfactory, the ring balloons 12-14 are finally inflated through the central filament lumens 22, again by a source of pressurized fluid external of the patient's body. Inflation of the ring balloons 12-14 causes them, in the manner of circumferential stiffening ribs, to fully expand the sleeve into tight sealing engagement with the interior surface 31 of the stomach vessel 32. The ends of the filaments 20,21 distal from the sleeve unit 10 are anchored to a posterior tooth or prosthesis by suitable fastening means or are sutured in place. The central or main lumens 22 of the filaments 20,21 are closed at these anchoring points by heat sealing, plugging, or the like, to indefinitely maintain a pressurized state in the connected ring balloons 12-14 to keep the adjacent sleeve areas in fluid-tight engagement with the stomach wall 31. Where desired, for example, to release fluids secreted by the stomach walls 31, the middle and lower ring balloons 13, 14 may be intermittently or permanently depressurized so that these fluids may pass through the remainder of the digestive tract. Alternatively, fluids secreted by the stomach area 31 shielded by the sleeve unit 10 may be aspirated through the oral cavity by way of the auxiliary lumens 23 and passages 26. Moreover, if desired, medicine may be carried into the annular zone defined between the sheath 11 and stomach walls 31 through the oral cavity by way of the auxiliary lumens 23 and passages 26.

The sleeve unit 10, by isolating the walls 31 of the stomach 32 from ingested food passing through it, reduces the digestive efficiency of the stomach. This results from interference with the normal contact of gastric juices, secreted by the stomach walls 31, on such food and the inability of the intestines of the lower digestive tract to absorb undigested food. Thus, the patient, while consuming food in even large quantities, is enabled to lose weight, since only a limited amount of the ingested food is ultimately absorbed.

Various other uses of the disclosed sleeve 10 or its equivalents are contemplated in the treatment of body disorders. For instance, the sleeve 10 may be disposed in the small intestine, rather than in the stomach, to directly reduce the effective area of the intestine available for absorption, again for the control of obesity. When disposed in the stomach, the sleeve may be utilized to medicate an ulcerous zone and isolate it from gastric juices to hasten normal recovery.

Referring now to FIG. 8, there is shown a second embodiment of the invention wherein a sleeve 25 is disposed within a human aorta 30 and associated right and left common iliac arteries 31, 32. The sleeve 25 is bifurcated at one end to provide a pair of branches 25*a* and 25*b* corresponding to the right and left common iliac arteries 31, 32 respectively. The sleeve 25 has a construction essentially the same as the earlier-described sleeve 10. Ring balloons 33 are spaced axially along the sleeve including the branch portions 25a, 25b. *Each of the ring balloons 33 is in fluid communication with at least one hollow filament 34,35 for purposes of inflation.*

The sleeve 25 is advantageously employed in cases of advanced blood vessel disease where a patient's tissue is such that it is impossible to sew or anastomose it with grafts or artificial vessels. An incision 41 is made in the vessel 30 to allow the positioning of the sleeve 25 therein. The sleeve 25 is expanded into position by directing fluid pressure into the elongated filaments 34,35 in any suitable manner such as dis-

closed above with use of free extensions (not shown) of these filaments.

The sleeve 25 is anchored in the vessel 30, for example, by sutures 42 near the incision 41, while the distal portion of the sleeve remains free. One or more holes 43 may be cut into the wall of the sleeve prior to placement within the vessel to provide blood flow to various arterial branches 46. The sleeve 25 is preferably formed of relatively inelastic material or otherwise is circumferentially reinforced with inelastic material along its length so that the pressure of blood flowing through the sleeve is effectively isolated from the vessel 30.

FIG. 9 illustrates another aspect of the invention wherein an inflatable ring balloon 50 is used to implant a prosthetic sleeve 51 at an area of a body vessel requiring expansion, reinforcement, isolation, or like treatment. The illustrated vessel 52 is a blood vessel previously blocked by plaque formation 53 and requiring expansion. A catheter 54 having a dilator annular balloon 50 at its free end and the sleeve 51 surrounding the balloon is threaded through the vessel 52 from an incision made in the vessel at a point remote from the area of plaque by known surgical procedures until the balloon and sleeve are within the area of blockage. When the balloon 50 and sleeve 51 are thus located within the plaque 53, the balloon is inflated to expand the plaque and the vessel 52. The balloon 50 has inner and outer imperforate walls 56, 57 which are circumferentially joined in a fluidtight manner at their ends. The annular space 58 between the sleeve walls 56 and 57 communicates with the lumen of the catheter tube 54. The balloon 50 is formed of any suitable plastic or rubber material which may be folded and/or expanded.

In a similar manner, the sleeve 51 has imperforate, flexible inner and outer walls 61,62 which are circumferentially joined in a fluidtight manner at their ends. An interior space 63 between the walls 61, 62 of the sleeve communicates with the interior of a tube 64 which extends along the catheter tube

54 to a point outside the vessel 52. The outer sleeve wall 62 may be formed of Dacron and can include a weave or mesh outer layer (not shown) which will lie against and adhere to the wall of the blood vessel. The inner wall 61 may be formed of Teflon so that cells will not readily adhere to this area.

The sleeve space 63 contains a fluid plastic material 66 which is caused to become solidified, preferably to a semirigid state after the balloon 50 has been expanded against the plaque 53. A suitable material for filling the sleeve space 63 Silastic **382,** medical grade elastomer, marketed by Dow Corning Corporation, of Midland, Mich., U.S.A. This material originates as two separate liquids: an opaque viscous elastomer base and a catalyst. The elastomer base is composed of polydimethylsiloxane and silica. The stiffness of this silastic material is controllable by varying the percentage of silica used. The concentration of catalyst can be varied, as prescribed by the supplier, to control the working time from four to one hundred minutes, as desired. Preferably, the components of the material 66 are thoroughly mixed and subsequently introduced into the sleeve space 63 just prior to the catheterization operation in which the balloon 50, sleeve 51, and catheter 54 are inserted into the vessel.

When being manipulated along the vessel, the balloon 50 and sleeve 51 encircling it are in an uninflated, collapsed state. The collapsed state can be maintained by wrapping the sleeve 51 on itself and superficially heat-bonding it at appropriate folds. The balloon 50, once in position within the area of the vessel to be treated, is inflated with a gas or fluid supplied under pressure through the catheter 54. The pressure of this inflating fluid is sufficient to break the light heat bonds holding the folds of the sleeve 51 together and to expand the sleeve and plaque 53 in the vessel 52 to the required degree. The inflation pressure is maintained for a period sufficient for setting of the liquid 66 in the sleeve space 63 to become solidified into its semirigid state. A central passage 68 in the

balloon 50 allows blood to continue to flow through the vessel 52 while the balloon is in place.

After the sleeve material 66 has solidified into a semirigid structure, the balloon 50 is deflated through the catheter 54 and is withdrawn from the sleeve by pulling the catheter. The sleeve 51 remains in place, with the stiffness of the material 66 preventing collapse of the vessel 52, and reducing the risk of dislodgement of particles of plaque into the bloodstream.

The tube 64 allows any gas given off by the setting sleeve material 66 during its solidification to escape to the atmosphere. Once the solidification reaction is effectively completed, the tube 64 can be removed by pulling on it and causing it to sever from the sleeve 51 at a point 69, where it is connected to the sleeve where a frangible thin wall section may be provided in the wall of the tube for this purpose. It is contemplated that the catalyst for setting of the material 66 can be encapsulated and mixed with the base and caused to release from such encapsulation upon the pressure applied thereto by expansion of the balloon 50. Another alternative is to introduce the settable material 66, including mixed catalyst, into the space 63 through the tube 64 after the sleeve 51 has been manipulated into position.

The invention is not restricted to the slavish imitation of each and every detail set forth above. Obviously, devices may be provided which change, eliminate, or add certain specific details without departing from the scope of the invention.

What is claimed is:

1. A method of treating an area of a body vessel, comprising the steps of: introducing a catheter with a collapsed inflatable annular balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated; manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated; inflating the balloon by introducing fluid under pres-

sure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel; providing in the sleeve a material which increases in rigidity after expansion of said balloon; maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity and body fluid is allowed to pass through the central aperture of the balloon; and thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated.

2. A method of treating an area of a body vessel, comprising the steps of: introducing a catheter with a collapsed inflatable balloon and a collapsed sleeve encircling the balloon on its end into the vessel at a point remote from the area to be treated; manipulating the catheter axially along the vessel to cause the balloon and sleeve to enter the area to be treated; inflating the balloon by introducing fluid under pressure into the balloon through a tube of the catheter in a manner wherein the sleeve surrounding the balloon is radially expanded towards the wall of the vessel; providing in the sleeve a material which increases in rigidity after expansion of said balloon; maintaining said balloon in an expanded condition in the vessel while said sleeve increases in rigidity; and thereafter removing the balloon and catheter from the vessel and allowing the sleeve to remain in place in the area to be treated.

END OF DOCUMENT